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INTRAVENOUS FLUIDS

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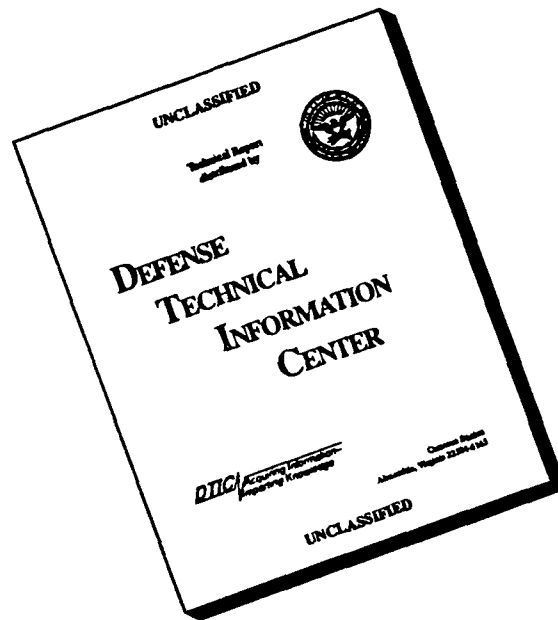
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PROJECT SUMMARY**

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IN-LINE MICROWAVE WARMER FOR BLOOD AND INTRAVENOUS FLUIDS

Technical Abstract (Limit your abstract to 200 words with no classified or proprietary information/data.)

Microwave technology has been used to develop a system capable of providing fast, in-line warming of blood or intravenous(IV) fluids. The first year of this Phase II program has resulted in the fabrication and testing of a functional engineering model consisting of four main components: (1) Microwave energy source with variable power control; (2) Heating Chamber with insertable cartridge; (3) Microwave radiometer for fluid temperature measurement; and (4) Feedback control algorithm on an IBM PC computer. The single most important technical achievement has been the integration of these major components into a functional closed-loop feedback control system.

To determine the efficacy of the rapid, in-line warming of blood and IV fluids within the microwave energy field, *in-vivo* tests using baboons have been conducted using a technique of radiolabelling blood components prior to microwave warming. Results show no significant changes in blood component longevity between samples that were warmed with microwave energy versus control samples warmed by a heated water bath.

The development work during the upcoming second year will consist of: (1) Fine-tuning the power control and temperature measurement components; (2) Optimizing the insertable cartridge of IV tubing; and (3) introducing a microprocessor system to replace the IBM PC computer.

Anticipated Benefits/Potential Commercial Applications of the Research or Development

The engineering model fabricated in the first year of the Phase II program can rapidly heat fluids using a feedback controlled microwave energy source. This technology is intended to result in a portable device for rapidly heating(in-line) blood or intravenous fluids administered in the pre-hospital treatment of hypothermia. An in-line unit overcomes the delay inherent with remote warming and the cooling occurring in a cold environment and/or in the transport of fluid or blood heated at a remote location.

List a maximum of 8 Key Words that describe the Project.

Trauma, Fluid Warming, Blood Warming, Hypothermia, Microwave

Nothing on this page is classified or proprietary information/data

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1.0 INTRODUCTION

1.1 Background

A general requirement exists to provide improved field care after traumatic injury when evacuation is delayed as described by Topic A87-284 in the DOD SBIR program solicitation of 9 January 1987. This topic asks for state-of-the-art applications designed to stabilize pathophysiological processes after traumatic injury.

Hypovolemic shock, secondary to traumatic exsanguination, is the most common cause of death in severely injured soldiers as identified by the Broad Agency Announcement guide for the U.S. ARMY Medical Research and Development Command of August, 1986[1]. Treatment of hypovolemic shock is the subject of this Phase II program being conducted by Microwave Medical Systems, Inc.(MMS).

Three important factors for successful treatment of hypovolemic shock include the administration of different types of fluids, rapidity of infusion of these fluids and prevention of hypothermia[2-5]. To address the problem of hypothermia and its associated coagulopathy occurring with trauma, Microwave Medical Systems Inc(MMS) has designed a device capable of in-line heating of intravenous(IV) fluids.

The intention of this Phase II program is to develop a portable device capable of in-line warming of blood or intravenous(IV) fluids administered to trauma victims in an emergency facility close to the battlefield. The design incorporates microwave energy for heating and passive, non-invasive microwave radiometry to monitor fluid temperature as shown in Figure 1-1. Unlike conventional in-line warmers, the microwave device will not require a heated water bath. The work completed in the first year of the Phase 2 program demonstrates the efficacy of the system and the feasibility of configuring the system into a small, portable unit that will provide controlled warming without invading the normal infusion pathway.

1.1.1 Battlefield Applications

The treatment of traumatic injuries occurring in the battlefield often requires restoring normothermia and infusion of fluids, such as saline or blood, into the patient. These two treatments are inter-related since the transfusion of cold fluids can further aggravate the hypothermic condition of the patient as shown by Boyan et. al[2]. Adverse effects on body physiology from hypothermia have been identified by many investigators including the USA Cold Regions Test Center in a report on "Arctic Personnel Effects"[6] and include the following:

- Decrease in heart rate, blood pressure, cardiac output and coronary blood flow[7-10].
- Reduction in tissue oxygenation. As body temperature drops, the affinity of oxygen for the hemoglobin molecule increases. This mechanism, in turn, impairs the transfer of oxygen from the hemoglobin molecule to the tissue[7,11].
- Heart failure in the form of ventricular fibrillation or ischemia. These conditions can result from myocardial cooling induced by the infusion of cold fluids into the central venous system[7-9].
- Loss of effectiveness of coagulation[7,9,11,12].
- Depressed hepatic function[7,12].

A 1985 clinical study by Slotman et al, showed that hypothermia(at temperatures less than 97°F) intraoperatively is associated with increased mortality[13]. These investigators recommend aggressive rewarming of hypothermic patients.

The recognition of hypothermia as a serious threat to the patient has led to the introduction of standard techniques to combat this condition. But these techniques are limited to the emergency room or operating room because conventional equipment to treat hypothermia is not portable. For mild cases of hypothermia, patients are usually warmed passively by apparatus such as warming blankets or heated rooms. For severe cases of hypothermia or for conditions involving hemodynamic compromise, patients are actively warmed by methods that heat the core circulation[7] such as inhalation of warmed vapor, gastric and/or peritoneal lavage and warmed, centrally-administered IV fluids.

The Phase 2 program addresses the need for an in-line fluid warmer that could be used in the field for the treatment of traumatic injury and associated hypothermia. A small, portable fluid warmer unit that is an integral part of the infusion path may help reduce the high mortality rates associated with the pre-hospital support phase of trauma by bringing the fluid-warming capability in close proximity to the patient. An in-line unit overcomes the delay inherent with remote warming and the cooling occurring in a cold environment during transport of fluid heated at a remote location. Currently, in-line administration of warmed IV fluids to the patient is accomplished in the operating room by commercially available heat exchangers which incorporate long lengths of tubing submersed in a warm water bath for heat transfer. This heat exchange instrumentation is impractical for field or ambulance use because it requires a large circulating volume of heated water. In addition, the long path length of these heat exchangers presents increased problems of blood coagulation or clotting.

IV FLUID & BLOOD WARMER: *Block Diagram*

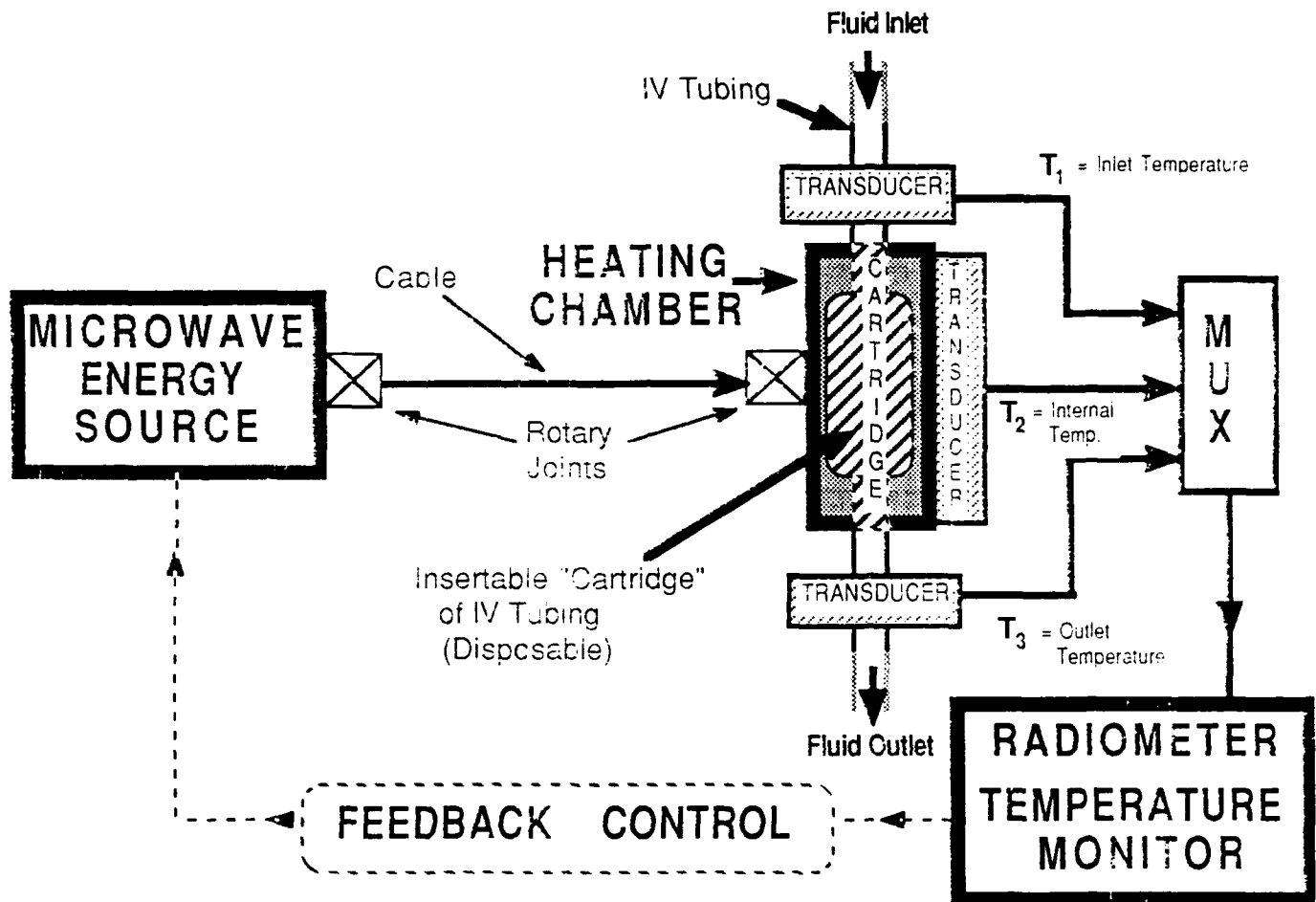


Figure 1-1. Block Diagram of Microwave IV Fluid/Blood Warmer with Radiometric Temperature Monitoring.

SYSTEM COMPONENTS:

- 1) **Microwave Energy Source**
 - This generator produces microwave power in excess of 400 watts at a frequency of 2450 MHz which warms the water-rich media flowing through the heating cavity.
- 2) **Heating Chamber + Cartridge of IV Tubing**
 - A cartridge, consisting of a labyrinth pathway of conventional IV tubing wound on a bobbin, is inserted into the heating chamber enclosure. Within this cavity the fluid is heated as it travels through the labyrinth by the energy supplied from the microwave generator. The plastic tubing carrying the fluids is transparent to microwave energy at this frequency. Cartridge design and orientation is optimized for most efficient absorption of the heating energy by the fluid.
- 3) **Radiometer Temperature Monitor**
 - Transducers measure microwave emissivity associated with thermal activity of fluids at three sites of the circuit:
 - Inlet Port of Heating Chamber
 - Interior Path of Heating Chamber
 - Outlet Port of Heating Chamber
- 4) **Feedback Control Mechanism**
 - This mechanism regulates fluid outlet temperature by controlling the power output.

TEST FIXTURE

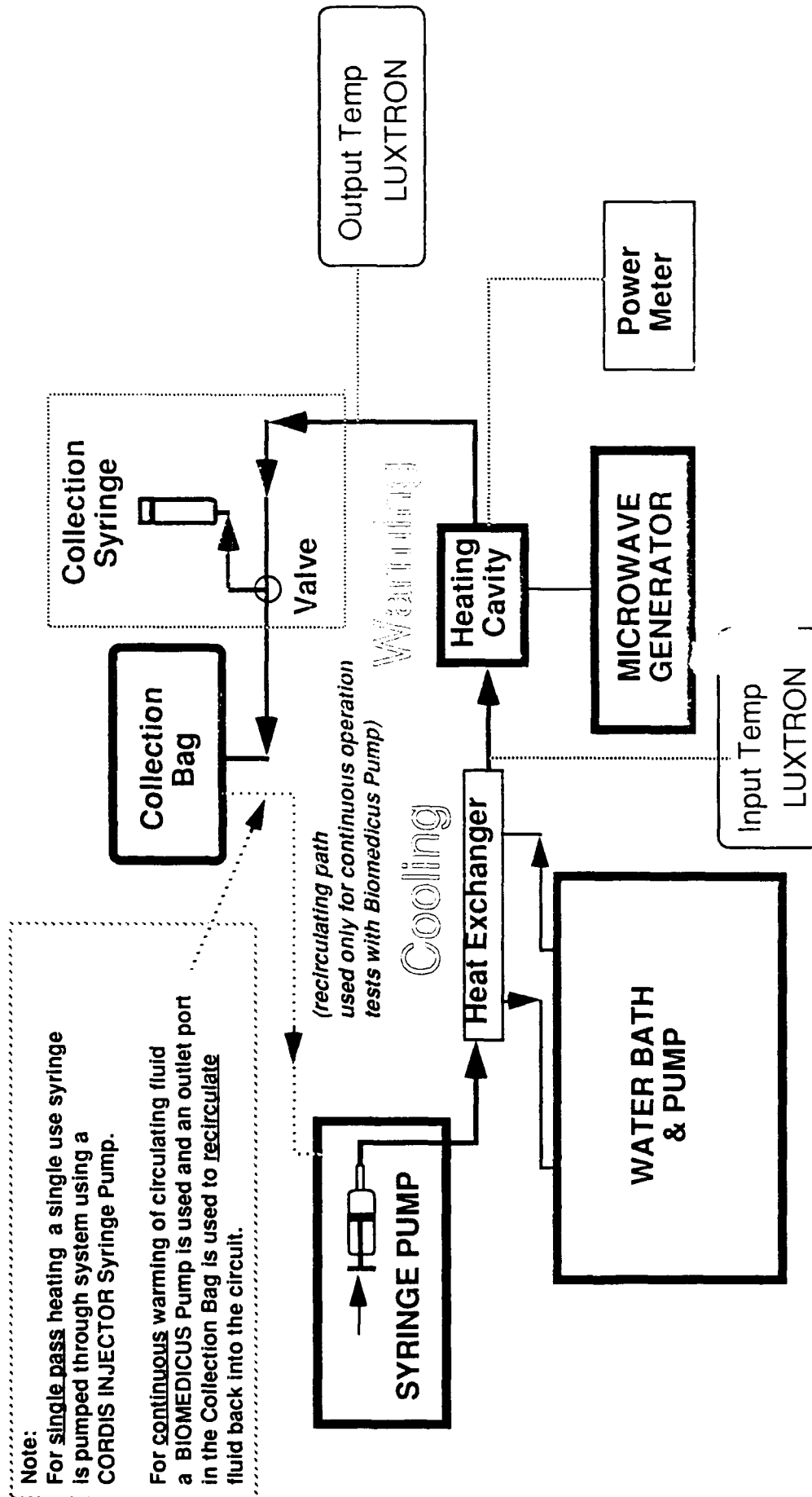


Figure 1-2. Test Fixture used to evaluate performance of Microwave Blood and IV Fluid Warmer
 The Cooling provided by the Heat Exchanger allows the fluid to be recycled in a closed loop circuit when continuous heating by the microwave generator is desired.

1.2 Objectives

The goal of the proposed Phase 2 program is to develop a portable blood and intravenous (iv) fluid warming system capable of rapid, uniform, and controlled heating of the fluids, in-line, during the infusion process. The system is being developed using the microwave heating technique and the radiometric temperature monitoring technique successfully demonstrated in the Phase 1 feasibility effort. A block diagram depicting this technique is shown in **Figure 1-1**. The evaluation of the system is being accomplished through use of a closed loop test circuit depicted in **Figure 1-2**. This test circuit can be used to heat iv fluids or blood on a continuous basis using a warming-cooling cycle.

The development of the Feedback Control mechanism is the single most significant development task of this Phase 2 program because it provides for System Integration of the two major subsystems:

- (1) Microwave Generator (*energy delivery*)
- (2) Microwave Radiometer (*temperature monitoring*)

The design of the engineering models for the Phase 2 program will be sufficient to start the final production phase (Phase 3) of the development sequence where support components, such as the sterile IV tubing cartridge, user interface, industrial design package and portable power supply, will be added.

In order to make available a final design that is best suited for current military applications, the design work done in the Phase 2 program is being performed in two steps:

- (1) **Phase 2A (year#1)**
- (2) **Phase 2B (year#2)**

The first year of development work, Phase 2A, was devoted to the development of an engineering model (**Engineering Model A**) for demonstrating the primary design goal:

Feedback control of the energy delivery source using the data sampled from the inlet and outlet fluid temperatures as inputs to the feedback control mechanism. The feedback control algorithm (ALGORITHM#1) controls energy delivery as a function of fluid temperature with a constant flow rate. The major components of Engineering Model A are:

- (1) Variable(coarse) Controlled Microwave Energy Source
- (2) Heating Chamber
- (3) Insertable Cartridge of IV Tubing
- (4) Microwave Radiometry Temperature Monitor(inlet&outlet)
- (5) Feedback Mechanism: IBM PC Hardware/Software
- (6) **ALGORITHM#1:** Energy = function(Temperature)

During the first year *in-vivo* tests were performed using baboons to evaluate the efficacy of the microwave blood warming technique.

The second year of development work, Phase 2B, will make available an engineering model (**Engineering Model B**) that will demonstrate the primary design goal:

System integration into one package for eventual configuration as a portable unit. The feedback control algorithm (ALGORITHM#2) controls energy delivery as a function of both fluid temperature and flow rate. The major components of Engineering Model B are:

- (1) Variable(fine) Controlled Microwave Energy Source
- (2) Heating Chamber
- (3) Snap-In Cartridge of IV Tubing
- (4) Microwave Radiometry Temperature Monitor(in,out,internal)
- (5) Feedback Mechanism: Microprocessor Hardware/Software
- (6) **ALGORITHM#2:** Energy = function(Temperature and Flow Rate)

During the second year *in-vivo* tests will be continued to evaluate the efficacy of the microwave blood warming technique.

ENGINEERING MODEL A

- Feedback Control implemented via IBM
Algorithm #1
Power = function (Fluid Inlet Temperature)
- Variable Power Control
- Temperature Monitoring Transducers interfaced to Radiometer via Multiplexer Electro-Mechanical Switch
- Hybrid Front-End of Radiometer

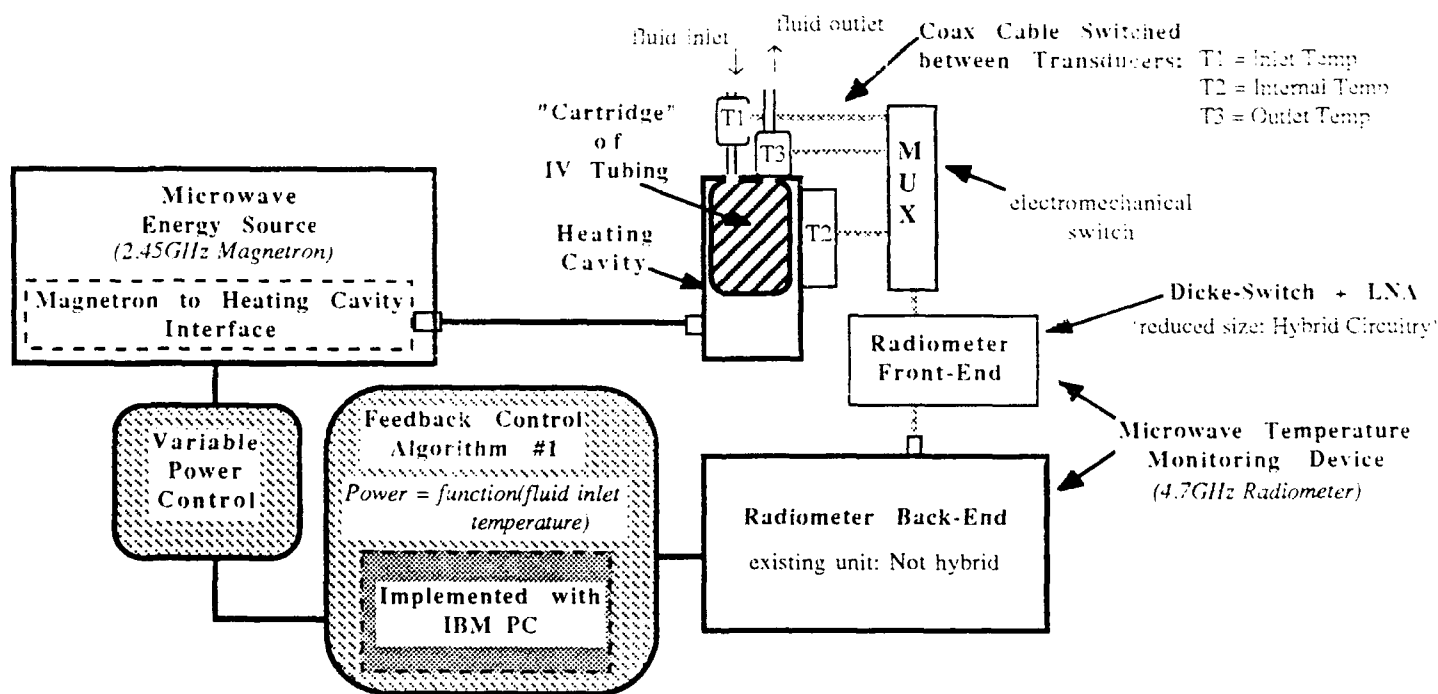


FIGURE 1-3. System Configuration for Engineering Model A (Phase 2A)

1.2.1 Phase 2A (Year #1) Objectives

The objectives of the Phase 2A program have been as follows:

- (1) Implement a Variable Power Mechanism
 - Use existing design of microwave generator (2.45 GHz Magnetron)
 - Develop solid state current control circuit for varying pulse width and duty cycle input to magnetron
- (2) Optimize Design of Heating Chamber and "Insertable Cartridge"
 - Optimize interface to magnetron with regard to efficiency and size.
 - Optimize "cartridge" design for small profile and ease of manufacture.
- (3) Optimize Design of Temperature Monitoring Transducers
 - Optimize transducer design for small profile and ease of manufacture.
- (4) Interface Microwave Radiometer for Temperature Monitoring
 - Electrically isolate 4.7 GHz radiometer from 2.45 GHz microwave generator (Magnetron)
 - Reduce size of existing radiometer to a small size unit (10" x 8" x 2.5") by replacing commercial Lock-In amplifier with a PC board design.
- (5) Implement **Algorithm#1** [Energy Delivery = Function(fluid temp)] on IBM PC
 - Interface radiometer output to IBM PC input
 - Interface IBM PC output to variable power controller input
 - Develop software for Algorithm#1
- (6) Construct **Engineering Model A** to Demonstrate 'Proof of Concept' of a Feedback Control Mechanism for Energy Delivery using **Algorithm#1**
 - Integrate microwave generator with microwave radiometer to provide simultaneous fluid warming and fluid temperature monitoring.
- (7) Determine System Performance of **Engineering Model A** with a Saline Fluid Flow Circuit
 - Verify radiometric measurements with thermocouple measurements.
 - Evaluate heating efficiency at various power levels.
 - Determine time response of feedback control mechanism for changes in fluid inlet temperatures.
- (8) Perform System Safety Testing with *In-Vitro* and *In-Vivo* Experiments
 - Use existing test circuit (Figure 1-2) for *In-Vitro* experiments.
 - Examine differences in blood constituency between microwave heated samples and control samples.
 - Evaluate constituency changes as function of: flow rate, power level, heating rate
- (9) Select a Development Path for the Phase IIB Program.
 - Review performance of the Phase IIA effort with the US ARMY.
 - Use criteria supplied by the US ARMY to determine optimal configuration for military applications.

1.2.2 Phase 2A (Year #1) System Configuration

The Phase 2A effort has worked toward the development of **Engineering Model A**, (Figure 1-3) consisting of five subsystems: Microwave Generator, Heating Chamber, Insertable Cartridge of IV Tubing, Microwave Radiometric Temperature Monitor and Feedback Control Mechanism (IBM PC). The interfaces that interconnect each of four subsystems are packaged outside of the main subsystem package.

1.2.3 Phase 2B (Year #2) Objectives

The objectives of the Phase 2B program are as follows:

- (1) Integrate Variable Power Control Circuit with Microwave Generator
 - Provide electrical shielding for control circuit
 - Provide user interface for switch-selectable power levels
- (2) Optimize Heating Cavity Design for Clinical Use
 - Integrate temperature monitoring transducers into a single package with heating cavity.
 - Optimize "cartridge" design for snap-in insertion and for quick connect/disconnect to IV infusion circuit.
- (3) Integrate Hybrid Radiometer (available from separate program) into System
 - Construct hybrid radiometer and incorporate into system.
- (4) Develop **Algorithm#2** (Energy Delivery = Function (fluid temp., fluid flow rate))
 - Develop software for Algorithm#2 on IBM PC
- (5) Develop Microprocessor Circuitry for Fast, Stand-Alone Feedback Control
 - Develop electronic hardware
 - Implement software for **Algorithm#2** on microprocessor
 - Interface microprocessor circuitry with power controller
- (6) Construct **Engineering Model B** to Demonstrate 'Proof of Concept' of a Feedback Control Mechanism for Energy Delivery using **Algorithm#2**
- (7) Determine System Performance of **Engineering Model B** with a Saline Fluid Flow Circuit
 - Verify radiometric measurements with thermocouple measurements.
 - Evaluate heating efficiency at various power levels.
 - Determine time response of feedback control mechanism for changes in fluid inlet temperatures and changes in flow rates.
- (8) Perform System Efficacy Testing with *In-Vitro* and *In-Vivo* Experiments
 - Use existing test circuit (**Figure 1-2**) for *in-Vitro* experiments.
 - Examine differences in blood constituency between microwave heated samples and control samples.
 - Evaluate constituency changes as function of: flow rate, power level, heating rate
- (9) Propose a Design to Pursue in Phase 3 for a Portable Field Unit.
 - Incorporate US ARMY design requirements.
 - Incorporate miniaturized radiometer.
 - Design a power entry module to supply power to entire system

1.2.4 Phase 2B (Year #2) System Configuration

At the start of the Phase 2B effort, the system configuration will be the same as **Engineering Model A** and ready for integration with a small Hybrid Radiometer. This Hybrid Radiometer is being developed by Microwave Medical Systems, Inc. in cooperation with M/A-COM, Inc. in a separate Phase 2 SBIR program funded by the National Institutes of Health (NIH) ("*Early Detection of Intravenous Cytotoxic Drugs*"). *Contract # N43-CM-57821*. By the time the Phase 2B effort begins, this 4.7GHz radiometer miniaturized using hybrid circuit technology will be available for integration into **Engineering Model B**.

Once the Hybrid Radiometer is integrated into **Engineering Model B**, development can continue with the optimization of each of the interfaces between the four major subsystems of the device: Microwave Generator, Heating Cavity, Microwave Radiometric Temperature Monitor and Feedback Control Mechanism. Size reduction of the interfaces and improved isolation between the four major subsystems will be the primary goal of Phase 2B. Additional size and cost reduction of the system will be achieved by incorporating a microprocessor for the feedback control mechanism. The resultant system, **Engineering Model B**, for Phase 2B will be configured as sketched in **Figure 1-4**.

ENGINEERING MODEL B

- Feedback Control implemented via microprocessor

Algorithm #2

Power = function (Fluid Temperature, Flow Rate)

- Temperature Monitoring Transducers and MUX are integrated with Heating Cavity
- Single Package for:
Generator + Feedback Mechanism
- Hybrid Radiometer: Front-End + Back-End

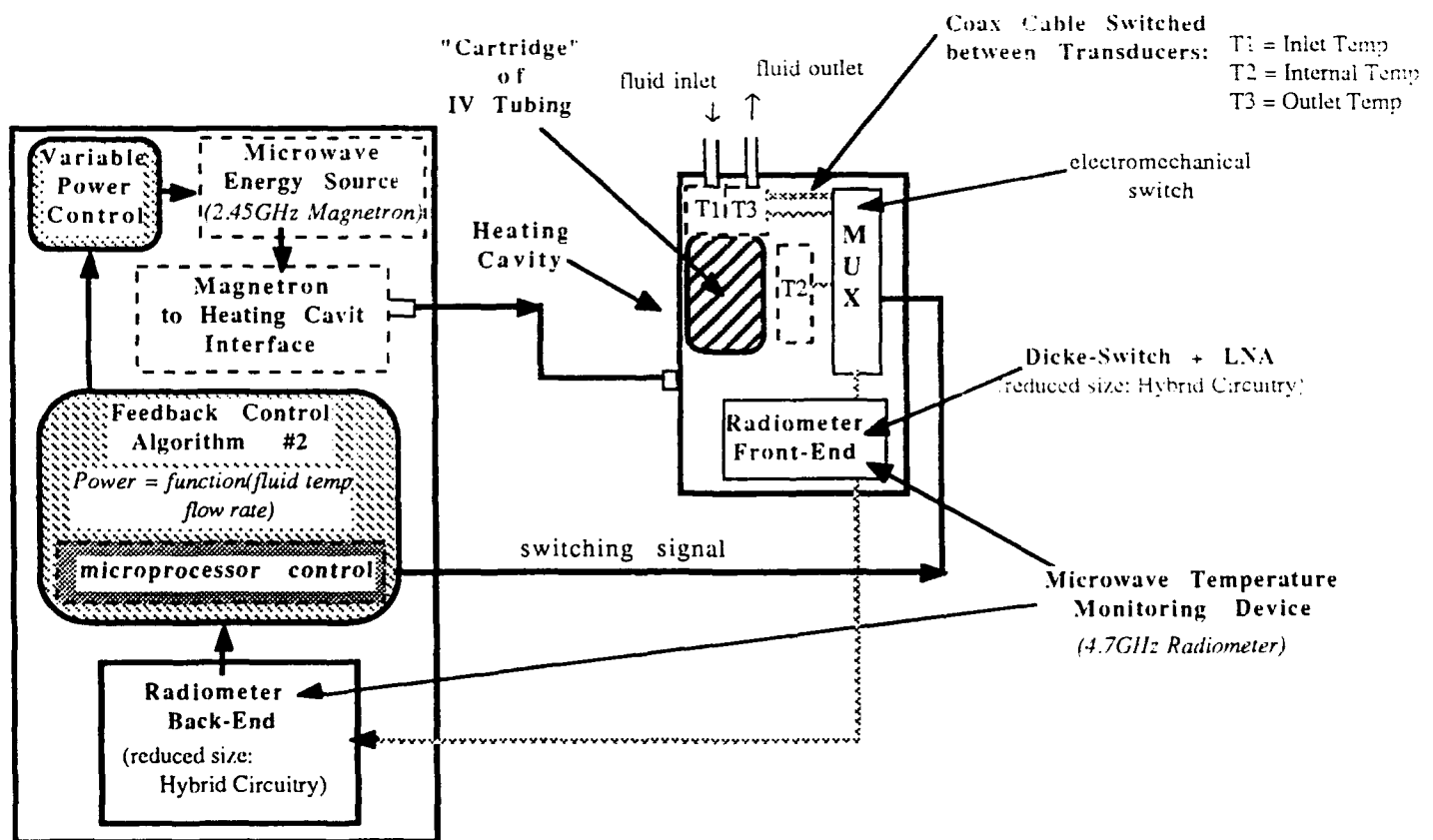


FIGURE 1-4. System Configuration for Engineering Model B (Phase 2B)

1.3 System Requirements

There are three major characteristics required for a system to warm blood and IV fluids in-line for infusion into trauma victims:

RAPID

Rapidity of heating a cold fluid to normal body temperature is essential, since the well-being of trauma patients depends on the speed of treatment. Infusion rates can range from 100 ml/min up to 500 ml/min.

UNIFORM

"Hot-Spots" are often associated with rapid warming, particularly with warming of fluids using conventional microwave ovens. The design of a microwave warming device customized for warming IV fluids, in particular blood, can provide a heating pattern that is without "hot-spots".

In studies investigating treatment of hypothermia by infusion of warm fluids investigators have suggested "safe" minimum and maximum temperatures for these fluids. Several investigators, including Russell[18] and the Finnish Red Cross Blood Transfusion Service headed by Linko[19,20], estimate that 32°C would be the minimum acceptable temperature for a blood warmer to maintain body temperature within the "safe" range. Additionally, the Finnish group[20], found that heating above 46.8°C caused hemolysis. These critical temperatures are guidelines to be used in the design of in-line blood/IV fluid warmers.

CONTROLLED

In order to provide warm fluid to the patient at a constant temperature, the rate of warming must be controlled as a function of the flow rate and temperature of the cool fluid entering the system.

Here, the accuracy of maintaining a constant temperature of the fluid to be administered to the patient depends on the sensitivity and response time of the sensors(or transducers) detecting temperature at various points in the flow circuit and the ability to use the sensor information efficiently in a feedback control loop. An additional requirement is that in order to maintain the sterility of the IV circuit, the sensors must be non-invasive. A technique that satisfies all of these requirements is microwave radiometry, which has been used in the past by Microwave Medical Systems, Inc.(MMS) to measure thermal activity passively and non-invasively in biological tissues[24-28]. For this application, radiometric transducers can be incorporated into the feedback control loop to monitor temperatures at various points in the flow circuit.

1.3.1 System Testing

In order to demonstrate and evaluate the performance of the microwave fluid warming system regarding the above three requirements, a test fixture(Figure 1-2) has been assembled and used in this Phase 2 study to measure the following:

- o **Heating Capacity of Energy Source**
Measurement of the temperature elevation of various fluids flowing through the system at specified flow rates.
- o **Effectiveness of Radiometric Monitoring of Temperature**
Sensitivity and response time of the radiometry system and transducers to detect the change in temperature of fluids flowing the circuit.
- o **Efficacy of Blood Warming**
Constituency of collected samples of blood warmed by the microwave heating device as compared to control(unheated) samples.

2.0 DISCUSSION

2.1 Development of Heating Chamber

The heating chamber is a waveguide cavity enclosure designed to transfer the microwave power from the microwave generator to the pathway of fluid in the IV tubing cartridge. The heating chamber is designed to operate at a center frequency of 2.45 GHz when the fluid-filled cartridge is in place inside the heating chamber.

Dimensional optimizations were made on the most recent design of the heating chamber. The previous design incorporated two inductive tuning posts which were located between the coaxial launch into the cavity and the back wall of the cavity. These tuning posts were eliminated, without compromise of spectral performance, with a dimensional modification of the cavity length, as seen in **Figure 2-1**. The heating chamber is coaxially coupled therefore it is able to be connected to the microwave generator via a stationary 50 Ohm coaxial connector or a high power flexible 50 Ohm coaxial cable. Engineering Model A, shown in **Figure 6-1**, displays the new reduced size heating chamber connected with a series of coaxial type "N" connector adapters.

2.2 Development of Snap-In Cartridge

The configuration of IV tubing wound around the cartridge which is inserted into the heating chamber has been designed to allow the most efficient uniform absorption of the microwave energy. We have achieved a design that contains a short length of only 18" of IV tubing wound around a cartridge to be inserted into the heating chamber. This short length of tubing assures that the blood will be exposed to only a minimal amount of additional tubing in addition to the normal IV path length. The improvement in design is depicted in the sketches of **Figure 2-2** where the original bobbin (used in the Phase I program), containing approximately 70" of IV tubing, has been replaced by the optimized cartridge containing 18" of IV tubing.

The cartridge is fabricated from Teflon and is press-fit into an aluminum cap which is mated to the top side of the heating chamber when the cartridge is inserted. The cartridge has been shown to accommodate at least two types of IV tubing without any degradation in heating performance, (four windings of 0.1" I.D. x 0.130" O.D. PVC tubing or three windings of 0.12" I.D. x 0.19" O.D. Silicone tubing).

2.3 Development of Variable Power Control

Several control mechanisms have been designed, fabricated and tested for controlling the magnetron, which generates the microwave power, such that the output power is a linear function of the control voltage. This control voltage is supplied by the feedback control mechanism, in this case a software/hardware interface on the IBM PC.

Power control using an auto-transformer was initially implemented to provide a variable 60 Hz AC voltage to the primary of the high voltage transformer which controls the magnetron. Linear power control was achieved with this method, however, the physical size and weight of such an auto-transformer made this method prohibitive.

In order to reduce the size and weight of the power control mechanism, a solid-state digital-timing power control circuit was designed and tested. This circuit uses a digitally controlled optically coupled Triac, a thyristor device, which acts as a switch to allow conduction of full 60 Hz cycles for a percentage of a 10 cycle period (approximately 167 milliseconds). For example, 3 cycles on and 7 cycles off corresponds to a 30% power level. This circuit controls the voltage to the primary of the high voltage transformer while a separate filament transformer maintains constant current. A timing diagram of this 10-level power control is shown in **Figure 2-3**.

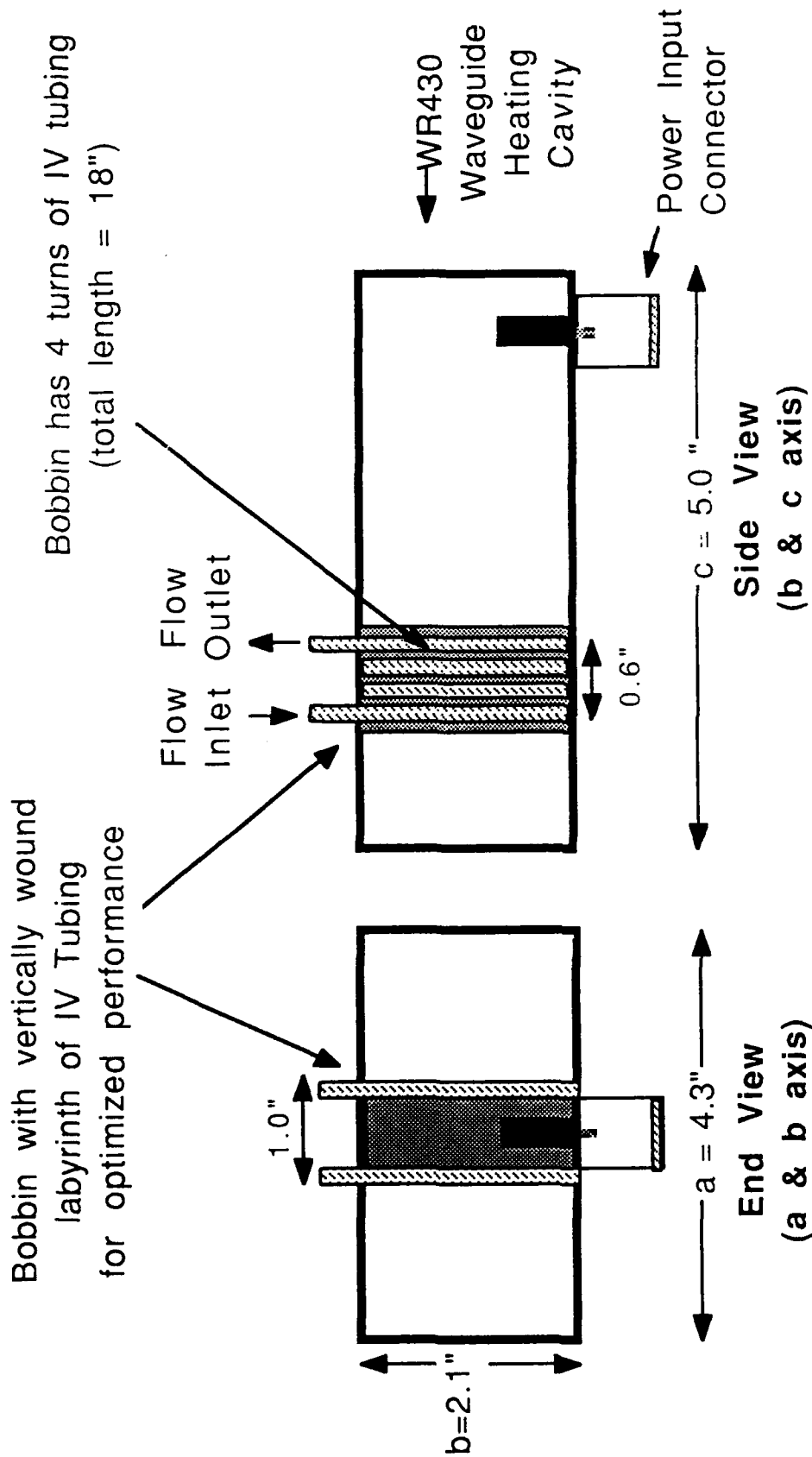
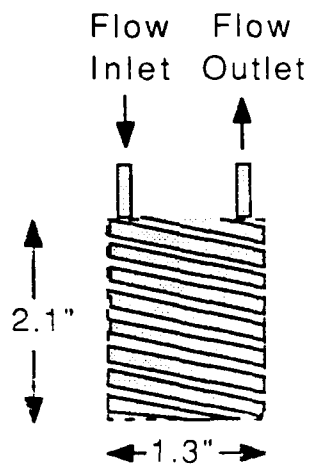
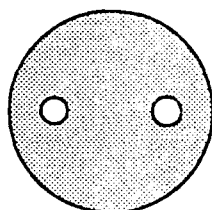


FIGURE 2-1. HEATING CHAMBER: Optimized Configuration
Bobbin & Tuning Configurations within Heating Chamber
designed to optimize performance.
Length of I.V. tubing in bobbin is approximately 18''



SIDE VIEW

(a)



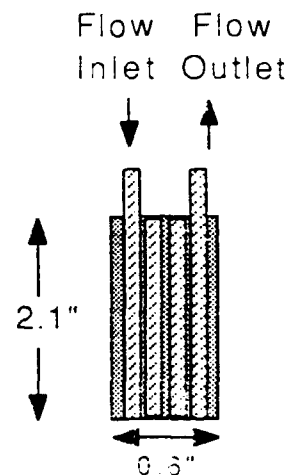
END VIEW

(b)

Figure 2-2 (a). Bobbin with Spiral of IV Tubing:

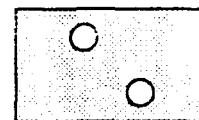
- 12 turns of IV tubing
 (I.D. = 0.10", O.D. = 0.14")
- Total length of tubing = 70"

(b) Bobbin End-Cap



SIDE VIEW

(c)



END VIEW

(d)

Figure 2-2 (c). Cartridge with Vertical Windings of IV Tubing:

- 4 turns of IV tubing
 (I.D. = 0.10", O.D. = 0.14")
- Total length of tubing = 18"

(d) Cartridge End-Cap

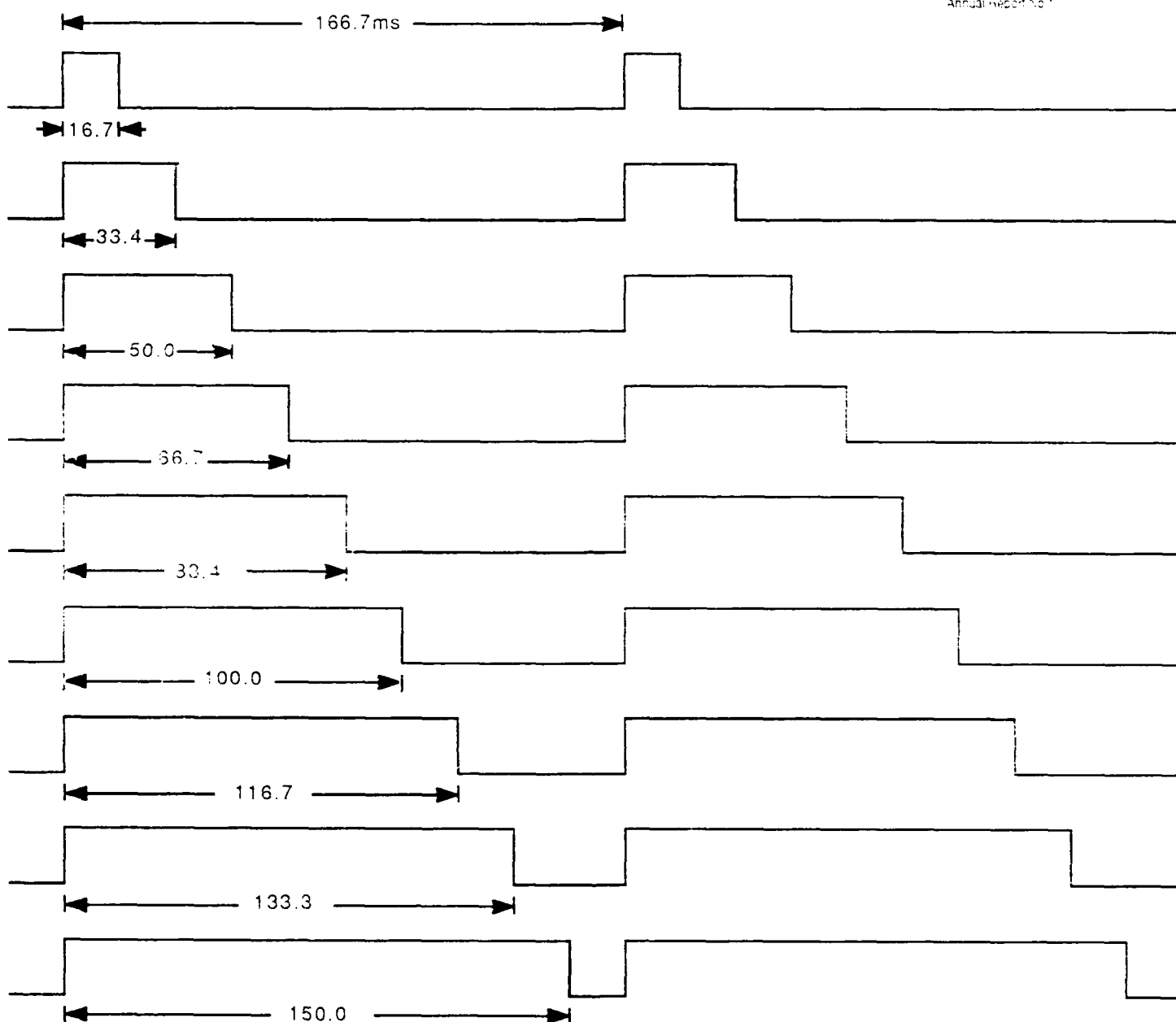


Figure 2-3. Timing Diagram for 10-Level Power Control Circuit used with Engineering Model A.

Currently, the power control circuit is fabricated on a large prototype board with its own internal power supply (10"x 6.5"x 3"). The small enclosure mounted on the I.V. stand of Engineering Model A seen in **Figure 6-1**, houses this prototype board with the power control circuit. This circuit is shown in **Figure 2-4**, and can easily be reduced onto a small circuit board and packaged into the microwave generator enclosure, (the larger enclosure mounted on the I.V. stand of **Figure 6-1**).

Experimental results of this method of power control revealed that output power is linear with the controlling voltage. The calculated output temperature variations for flow rates ranging from 0 to 500 ml/min using 10-level power control of the 400 Watt microwave generator is displayed in **Table 1a**. To achieve finer control of output power to further reduce the temperature variations over a wide range of flow rates and ΔT 's, a power control circuit with finer control will be developed in year #2 of this Phase 2 program.

2.4 Development of Temperature Monitor

During year #1, a radiometer developed in a separate program using hybrid microwave circuit components was used in Engineering Model A of this Phase 2 Program. The completed packaged hybrid radiometer is shown in **Figure 2-5**. This unit has the capability of either monitoring the absolute temperature sensed by a single transducer (antenna), or the differential temperature sensed between two transducers. In the differential mode, the differential temperature between the inlet and output ports of the system can be monitored on a continuous basis. Optimization of the individual temperature-sensing transducers for the inlet and outlet fluid ports has been completed in year #1 of this Phase 2 Program.

Transducers for in-line measuring of emissivity associated with thermal activity of fluids at the inlet and outlet ports of the heating chamber have been designed and integrated into Engineering Model A. These transducers receive thermal emissions at a center frequency of 4.7 GHz and send a temperature equivalent signal to the microwave Radiometer for feedback control of the power delivered to the heating chamber. The transducer has been redesigned for size reduction to accommodate two such elements in a single package with a third transducer for inside cavity temperature measurement.

The new transducer for in-line temperature monitoring has been reduced to approximately one-third the size of the previous transducer used in the Phase 1 Program, as seen in **Figure 2-6**. To ensure the isolation of interference with the microwave generator, small shielding tubes are placed at the input and output of the transducer. Receiving performance of these radiometric transducers demonstrates a 10 dB bandwidth of 250 MHz as measured on the Wiltron 560 Scalar Network Analyzer. The output response times of the Radiometer with changing output temperature of fluid flowing through the transducer can be adjusted in Engineering Model A. to obtain the optimum response time trade-offs with resolvable temperature change.

Although we have been successful in electromagnetically isolating the radiometric temperature monitoring subsystem from the interference of the microwave energy source for the inlet and outlet transducers, isolation for the transducer internal to the heating chamber remains a problem. This task will be continued into the second year of development. An alternative approach for monitoring the temperature of the fluid inside the heating chamber is being researched. This alternative method involves monitoring the reflected power from the heating chamber, to take advantage the change in reflected power occurring when the temperature of the fluid changes. This technique has been used successfully by Microwave Medical Systems, Inc. on other applications and this technique is worthy of merit here. This approach will be researched during the next quarter.

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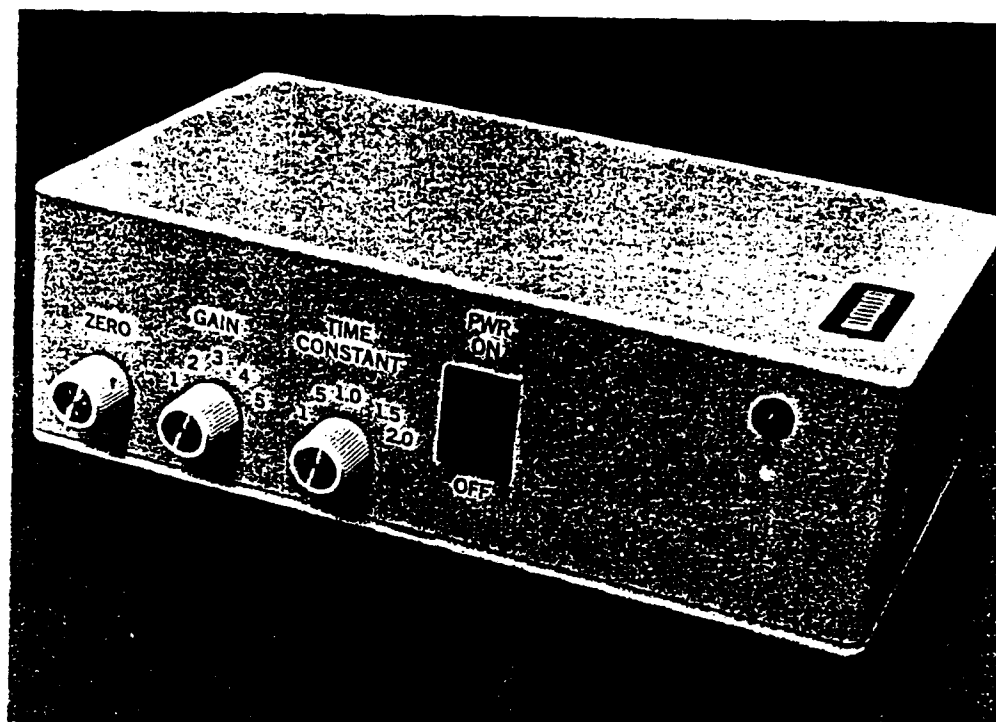


FIGURE 2-5(a) MINIATURIZED BACK-END OF RADIOMETRIC
EXTRAVASATION DETECTION (RXD) SYSTEM

ACTUAL SIZE IS : 7.5" x 4.5" x 2.3"

NOTE: Size of miniaturized Front-End (not pictured) is: 4" x 2" x 1"

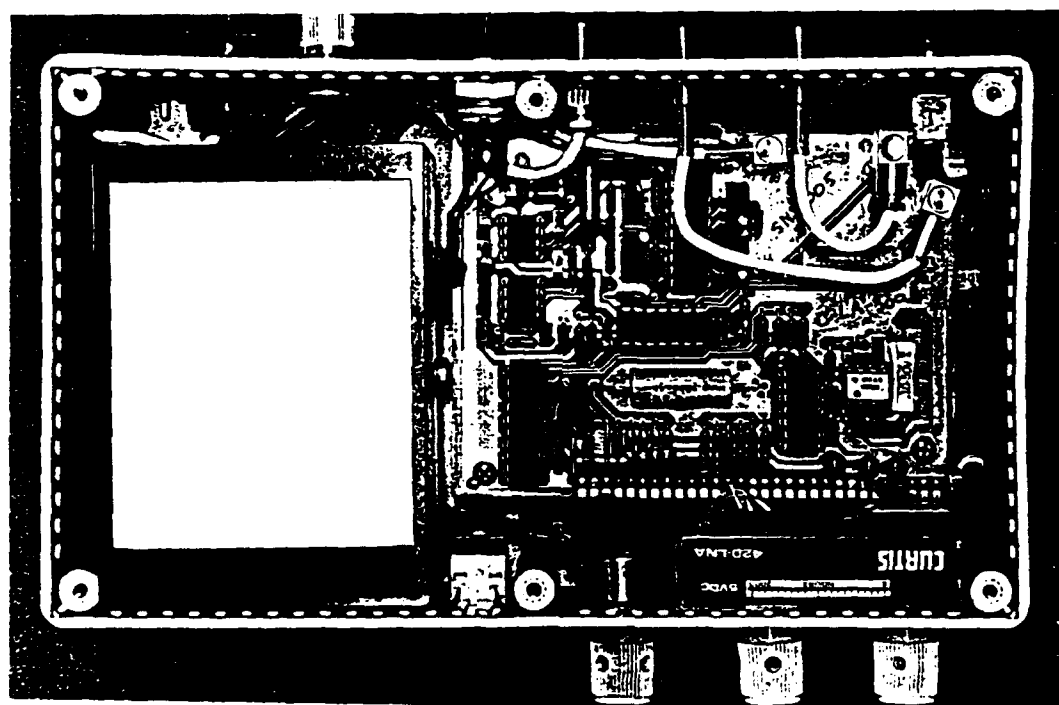


FIGURE 2-5 (b) BOTTOM VIEW OF CIRCUITRY WITHIN RADIOMETER

MAJOR COMPONENTS: 2nd Amplifier Stage, Bandpass Filter, Square Law Detector, Lock-In Amplifier, Synchronization Clock, Alarm Detection and Indicator Mechanism, Power Supply

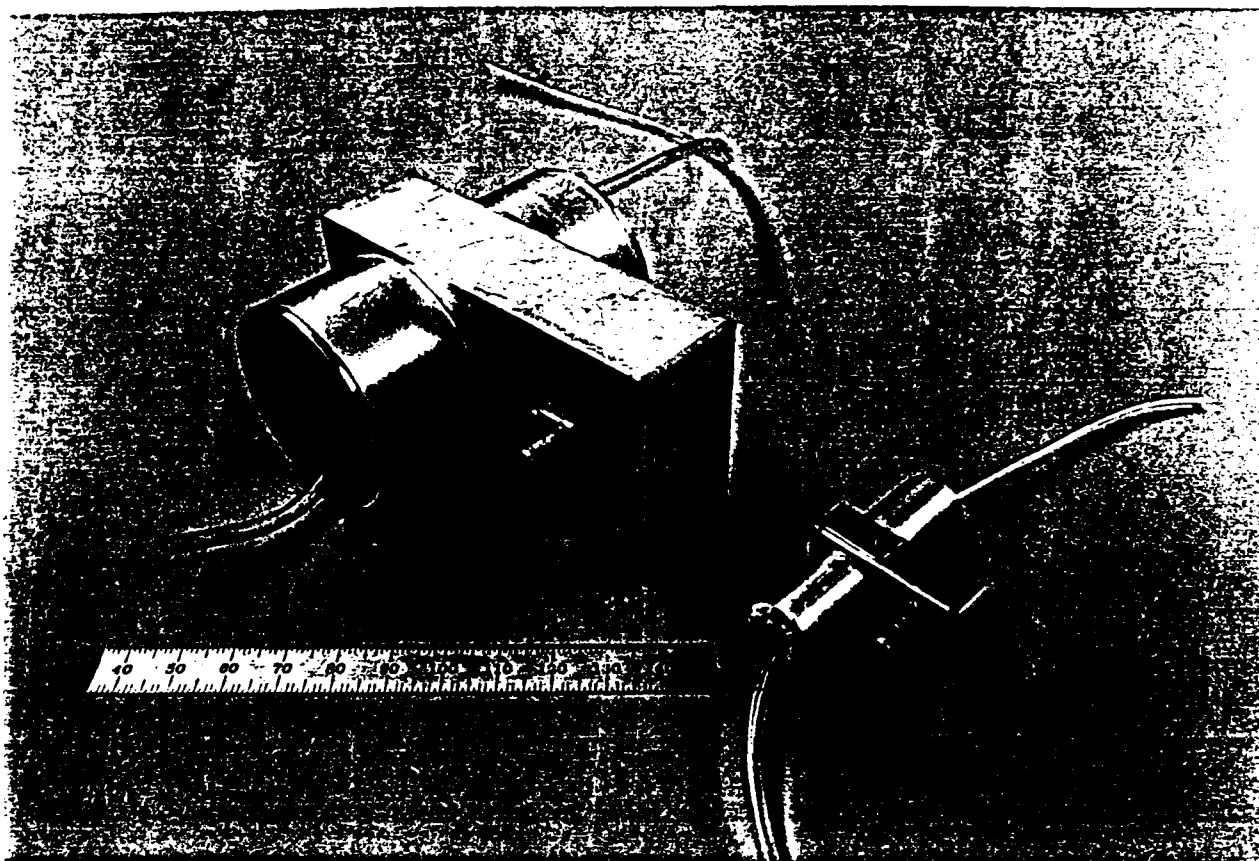


Figure 2-6. Reduced size temperature transducer used to monitor inlet and outlet fluid temperatures for feedback control of Engineering Model A. Shown with previous design which is three times the size.

2.5 Development of Feedback Control

A real-time control software and hardware system has been implemented on the IBM PC and setup so that it can be interfaced to the radiometer for temperature input and to the power control circuit for output of a control voltage. The software/hardware interface uses a commercially available interface card (Data Translation Model DT2808) with on-board Analog-to-Digital Converters (ADC's) and Digital-to-Analog Converters (DAC's) that plugs into the backplane of the IBM PC.

Software has been written in the C Language for real-time operation and monitoring of the variable power module and temperature sensing module of Engineering Model A. The software consists of approximately 50 pages of source code and a run-time module which occupies 305 KBytes of memory. Features in this software package include: (1) A menu providing for user selection of operating parameters and system control is shown in **Figure 2-8**; (2) A graphic display of all inputs and outputs during real-time system operation as shown in **Figures 2-7** and **6-2**; and (3) Facilities for easy manipulation of algorithm changes.

Algorithm #1 has been implemented in software on the IBM PC. This algorithm is based on controlling the power as a function of fluid inlet temperature. The outlet temperature, T_o , of the fluid remains constant for changes in inlet temperature, T_i , by varying the power level supplied to the heating chamber. This algorithm provides a classic PID control of the power output in response to the inlet and outlet temperatures. In addition a user-friendly, graphic interface has been implemented for on-line, real-time operation of the system. Parameters such as flow rate, fluid type (saline or blood) and desired outlet temperature can be easily entered by the user. The graphic screen output is displayed in real-time and allows the user to observe the inlet temperature, outlet temperature and power output as monitored and controlled by the system in real-time.

Figure 2-7 shows the PID response of the algorithm when a simulated square wave signal for the outlet temperature is presented to the input of the system. In this figure the target temperature is 35°C . With the square wave outlet temperature varying between 33.9°C and 36.2°C we see that the response of the control signal for the output power is the expected triangular wave response, characteristic of a classic PID feedback control algorithm. A display of actual inputs and outputs during a fluid warming trial is shown in **Figure 6-2**.

2.6 System Integration

The single most significant task of year#1 of this Phase 2 program has been accomplished: The in-line fluid temperature measurement module has been linked together with the fluid warming module via a feedback control mechanism resulting in a functional system (Engineering Model A). The feedback algorithm has been successfully implemented on an IBM PC computer which interfaces to both the temperature measurement module and the fluid warming (or power delivery) module.

Figure 6-1 shows a photograph of Engineering Model A in its final configuration for year#1 of this Phase 2 program. These major components of Engineering Model A (not including the IBM PC Computer) are packaged in 5 distinct packages and interconnected to form a functional unit as follows:

ITEM	DESCRIPTION	SIZE (in inches)
(1)	Energy Source Module	5.3 x 9.5 x 17
(2)	Power Control Module	5.3 x 7.5 x 12
(3)	Radiometric Temperature Monitor Module (part1)	2.3 x 4.5 x 7.5
	(part2)	1.0 x 2.0 x 4.0
(4)	Heating Chamber	2.5 x 4.5 x 5.3
(5)	Cartridge(insertable into heating chamber)	1.0 x 1.3 x 2.5

For Engineering Model A, the five modules listed above are mounted on an IV stand and connected to an IBM PC Computer. This system is capable of controlling the outlet temperature of the fluid to less than $\pm 1.5^{\circ}\text{C}$ of the target temperature when fluid is flowing at 200 ml/min. This performance level demonstrates a proof of concept of the closed loop technique and will be refined to give finer control ($\pm 1^{\circ}\text{C}$) in year#2.

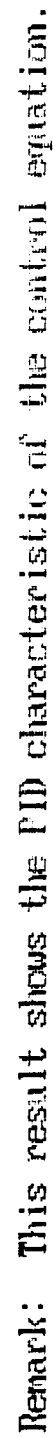


FIGURE 2-7. Actual Output(on IBM PC graphics display) from Engineering Model A illustrating Response of Feedback Algorithm.

Blood warmer test control loop set up screen
 Microwave Medical Systems, Inc.

CURRENT VALUES	SELECTIONS
	(0) Quit blood warmer experiment.
	(1) Set up O.K., GO TO next screen.
35.00 °C	(2) Set up Delivering temperature.
WATER	(3) Toggle fluid type.
200.00 ml/sec	(4) Set up flow rate.
10.315 msec	(5) Set up new external trigger.
	(6) Set up control constant.
0.00 °C	(7) Set up reference temperature.

Select 0 - 7:

FIGURE 2-8a. Actual Display Screen (on IBM PC graphics display) of MENU Selectable Functions/Parameters

Blood warmer test control loop set up screen
 Microwave Medical Systems, Inc.

CURRENT VALUES	SELECTIONS
	(0) Quit blood warmer experiment.
	(1) Set up O.K., GO TO next screen.
35.00 °C	(2) Set up Delivering temperature.
WATER	(3) Toggle fluid type.
200.00 ml/sec	(4) Set up flow rate.
10.365 msec	(5) Set up new external trigger.
	(6) Set up control constant.
0.00 °C	(7) Set up reference temperature.

EXAMPLE: Select Function (6)

Current control eq:: $C1 * K * (Temp_ref - Temp_out) * (Temp_ref - Temp_in)$
 Current Constant C1 = 0.000100
 Select 0 - 7: Type in Constant C1 =

FIGURE 2-8b. Example of Selecting Function (6) for Setting Constants in Feedback Algorithm

The IBM PC computer is used to monitor the operation of Engineering Model A via a real-time graphics display that monitors all of the system input and output signals during operation. **Figure 6-2** shows the response of the algorithm during actual system operation of Engineering Model A. The signal for the inlet and outlet temperature as measured by the in-line temperature transducers through the radiometer, is presented to the input of the feedback system. In this figure the target temperature is 35°C and the starting conditions are such that the inlet and outlet temperatures are just below 10°C when the output power is at a maximum level. As the outlet temperature increases, the output power remains at the maximum level until the outlet temperature increases to a level just above the target temperature of 35°C. Once this occurs, the output power decreases to permit the outlet temperature to slightly decrease. Once the temperature has dropped just below the target temperature of 35°C the output power increases to maintain the target temperature. These oscillations around the target temperature are determined by the system performance of Engineering Model A, which is determined by a \pm error value around the ideal ΔT . This error term is directly related to the amount of available power levels, therefore acquisition of target temperature is within $\pm 1.5^\circ\text{C}$ for a fluid flow rate of 200 ml/min, and will be improved to give finer control in year #2. The initial overshoot of the target temperature as seen in **Figure 6-2**, is due to the feedback system response which can be selected to perform optimally in year #2 of this Phase 2 Program.

3.0 DOCUMENTATION

3.1 List of Quarterly Reports

Progress for each of the four quarters of the first year of this Phase 2 program has been reported in quarterly reports submitted at the end of each quarter to the following address: Commander, Letterman Army Institute of Research, Attn: SGRD-ULZ-RCD/Ms. McHenry, Presidio of San Francisco CA 94129-6815.

The content of these quarterly reports is summarized can be summarized as follows:

Quarterly Report #1

Time Period Covered: 1-Dec-88 to 28-Feb-89
Date Submitted: 15-Mar-89
Content: Description of: (1) Preparing Existing Devices and Equipment for Use in Phase 2, (2) Building Radiometer with existing design and parts, (3) Developing Interface from IBM PC to Power Control Module, (4) Developing Interface from IBM PC to Temperature Monitor Module.

Quarterly Report #2

Time Period Covered: 1-Mar-89 to 31-May-89
Date Submitted: 15-Jun-89
Content: Description of: (1) Completion of the Radiometric Receiver for Use in Temperature Measurement, (2) Optimizing the IV Tubing Path within the Cartridge, (3) Planning in-Vivo Experiments (4) Initiating work on the Feedback Control Algorithm (5) Initiating Fabrication of Engineering Model #A.

Quarterly Report #3

Time Period Covered: 1-Jun-89 to 31-Aug-89
Date Submitted: 15-Sep-89
Content: Description of: (1) Start of In-Vivo Experiments (Description of preliminary results), (2) Implementing the Feedback Algorithm on the IBM PC, (3) Evaluating Power Control Methods for Power Module.

Quarterly Report #4

Time Period Covered: 1-Sep-89 to 30-Nov-89
Date Submitted: 15-Dec-89
Content: Description of (1) Linking together of the Variable Control Power Module with the Temperature Monitoring Module with a Feedback Control Mechanism as provided by an IBM PC computer, (2) Completion of the In-vivo animal experiments.

Only a brief synopsis of the above two activities are given in the Fourth Quarterly report; an in-depth report of these two activities is given here in the annual report of year#1.

3.2 Presentations

In addition to the quarterly reports listed above, a presentation of the microwave technology involved in the fabrication of Engineering Model A and a review of the *in-vivo* testing techniques was given on October 26, 1989 to Captain Stephen P. Bruttig of the Letterman Army Institute of Research.

4.0 STATUS OF THE PHASE 2 PROGRAM

4.1 Review of Milestones for Year#1

The task schedule and list of milestones for year#1 is presented in **Chart #1**. The work performed during year#1 has resulted in the successful completion of **Engineering Model A** as shown in **Figure 1-3**, with the exception of the monitoring transducer for the temperature of the fluid internal to the heating chamber (temperature monitoring at the inlet and outlet ports of the heating chamber is fully operational). In-vivo testing of the microwave technique using animals(baboons) has been successfully completed during year#1. A brief *in-vitro* test involving warming whole blood withdrawn from human volunteers has been rescheduled to year#2.

Demonstration of the two Main Modules of this System (Variable Power Control Module and Temperature Monitoring Module) were given on October 26, 1989 during a site visit by Captain Stephen P. Bruttig of the Letterman Army Institute of Research. Subsequent to this site visit, these two main Modules were integrated into single system: **Engineering Model A** with a functional closed-loop feedback mechanism. **Engineering Model A** is a functional system that demonstrates the capabilities of fluid warming and fluid temperature monitoring using microwave technology. The feedback control mechanism implemented here is capable of regulating the outlet temperature of fluid heated by the system to a tolerance of $\pm 1.5^{\circ}\text{C}$ at a typical flow rate of 200 ml/min.

As shown in **Chart#1** all tasks have been completed with the exception of **Task #A8** and **Task #A15**.

- **Task#A8** relates to the monitoring of the fluid temperature internal to the heating chamber. The efforts on this task year#1 proved that the temperature internal to the heating chamber could be monitored successfully when the power to the heating chamber was off. With the power on, more isolation between the Microwave Energy Source(2.45 GHz) and the Radiometric Temperature Monitor(4.7GHz) is required to achieve accurate temperature measurement. This task will be completed in year#2 of the Phase 2 program by incorporating more isolation, or, if unsuccessful, by incorporating a different approach using reflected power measurement from the heating chamber.
- **Task#A15** relates to the *in-vivo* and *in-vitro* testing of the microwave technique. The most significant portion of this task, the *in-vivo* testing using animals has been completed. Experiments involving the *in-vitro* testing of fresh whole blood drawn from human volunteers has been moved to year#2 because of the delay in obtaining approval from the Human Investigational Review Board at New England Medical Center.

4.2 List of Milestones for Year#2

The task schedule and list of milestones for year#2 is presented in **Chart #2**. The expected result of this effort will be the development and fabrication of **Engineering Model B** as shown in **Figure 1-4**.

MMS, Inc.
rev 0.6
15-Nov-89

MILESTONE CHART FOR PHASE 2A (year#1) of MICROWAVE BLOOD IV FLUID WARMER

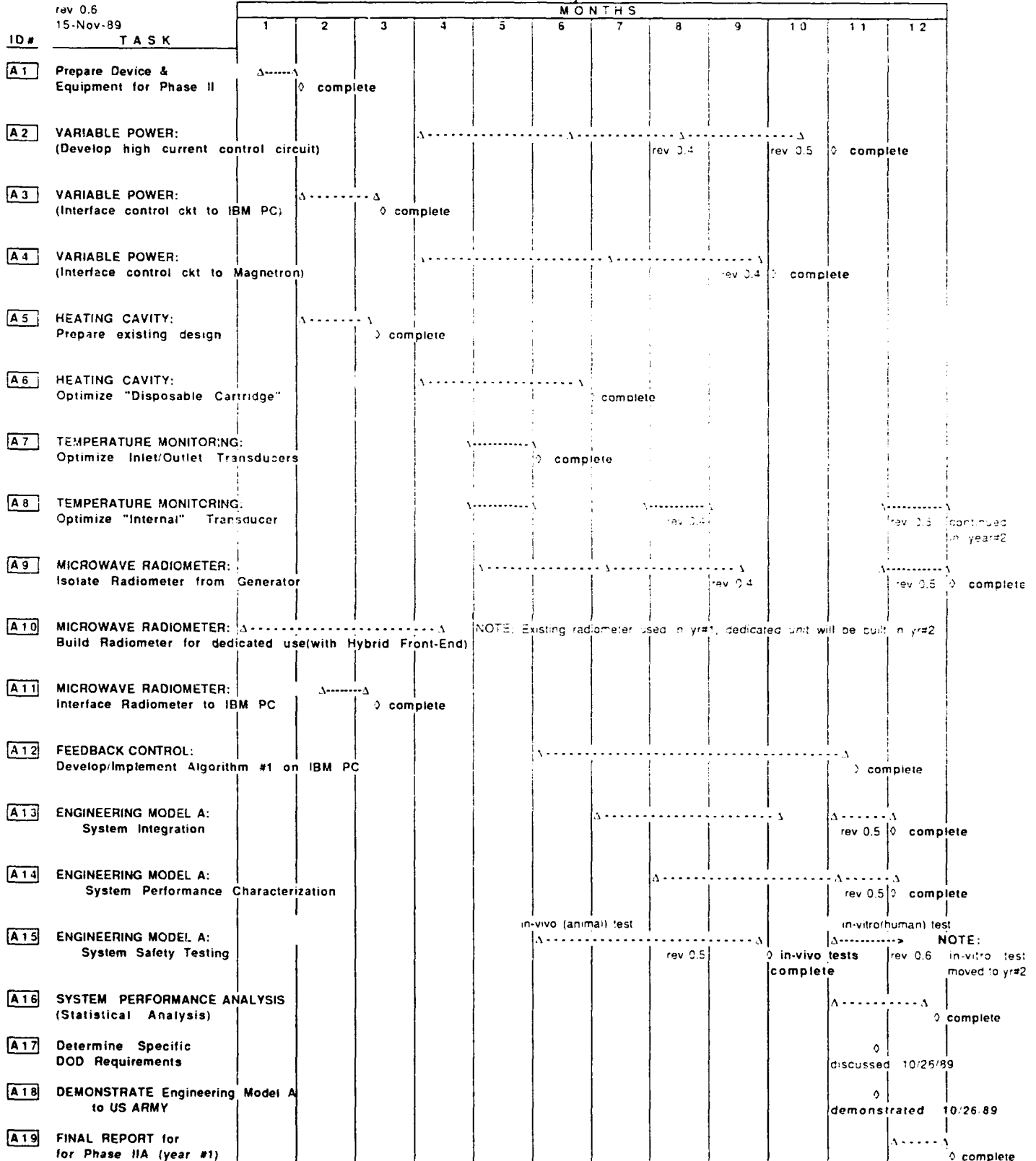


CHART 1. MILESTONE CHART FOR PHASE 2A (year#1) of MICROWAVE BLOOD IV FLUID WARMER

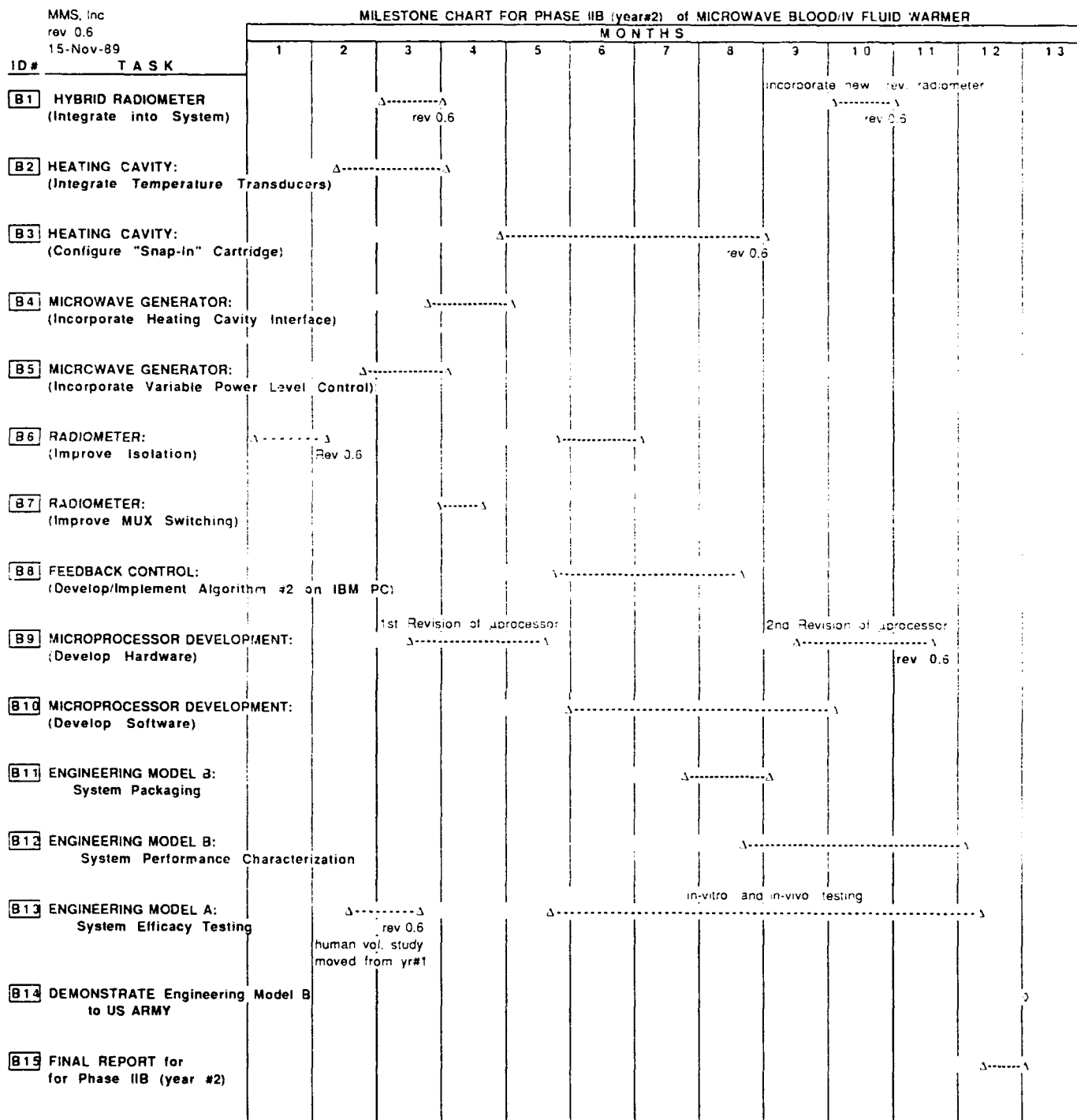


CHART 2. MILESTONE CHART FOR PHASE 2B (year#2) of MICROWAVE BLOOD/IV FLUID WARMER

5.0 TESTING METHODS

5.1 Microwave Characteristics of Heating Cavity

This waveguide cavity enclosure is designed to transfer the microwave power from the microwave generator to the pathway of fluid in the IV tubing cartridge. The heating chamber is designed to operate at a center frequency of 2.45 GHz with a 15 dB bandwidth of approximately 200 MHz when the fluid filled IV tubing cartridge is inserted. Return loss data taken with a Wiltron Model 560 Scalar Network Analyzer, shown in **Figure 5-1a**, verifies that approximately 97% of the microwave power is transferred to the I.V. fluid as it flows through the heating chamber. The wide cavity bandwidth, 200 MHz, is necessary to ensure that the full amount of available power will be coupled into the heating chamber. The output power spectrum of the microwave generator taken from an HP 8562A Spectrum Analyzer, shown in **Figure 5-1b**, indicates that the available power is spread over approximately 100MHz and is centered at 2.456 GHz, which is well within the 200 MHz heating chamber 15 dB bandwidth.

5.2 Heating Capacity of System

Figure 5-2, shows the system power requirements for flow rates from 25 to 500 ml/min. These values were determined as follows:

$$P = (k \cdot p \cdot c \cdot \Delta T)(Q/60) \quad \text{Eq. (5-1)}$$

where:

P = Power in Watts, 1 watt = 1 Joule/sec
 k = 4.184 Joules/calorie
 p = 1 gm/ml for water, = 1.05 gm/ml for blood
 c = 1 cal/gm°C for water, = 0.93 cal/gm°C for blood
 ΔT = Temperature difference in °C ; $\Delta T = T_{\text{output}} - T_{\text{input}}$
 Q = Volumetric flow rate in ml/min

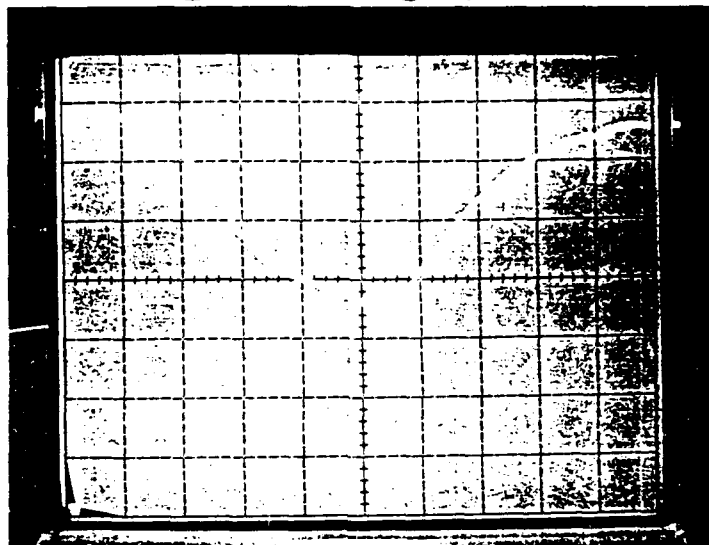
The microwave power generator used in Engineering Model A, has 400 Watts of available power with 10% power levels ranging from 0 to 100%. **Table 1a**, displays for each flow rate (25 to 500 ml/min), the ideal power level, the available power level, and the power error (ideal power - available power). This **Perror** is converted into a **Terror** by using the above **Equation 5-1** and is shown in **Table 1b**. The $\pm \text{Avg. } \Delta T_{\text{error}}$ for each given flow rate is displayed in the column to the far right of **Table 1b**. The **Terror** is subtracted from the ideal value of ΔT , and the output results are displayed at the bottom of **Table 1b**.

For example:

- In **Table 1a**, at a desired ΔT of 33 °C and a flow rate of 175 ml/min, the ideal power needed is 402.7 Watts.
- The available power with the 10-level power control is 400 Watts.
- Therefore, the **Perror** equals (402.7 - 400) which is a difference of +2.7 Watts.
- The **Perror** is converted to a **Terror** of +0.2°C, and then the $\pm \text{Avg. } \Delta T_{\text{error}}$ is calculated for all ΔT 's at flow rate = 175 ml/min to be 0.8°C, as seen at the top of **Table 1b** and graphically displayed in **Figure 5-4**.
- The actual temperature change can then be calculated as follows: 33°C - 0.2°C = 32.8°C. Each column corresponding to a ΔT in the range of 1°C to 34°C is separately tabulated to attain a ΔT_{max} , ΔT_{min} , and $\pm \text{Avg. Terror}$.

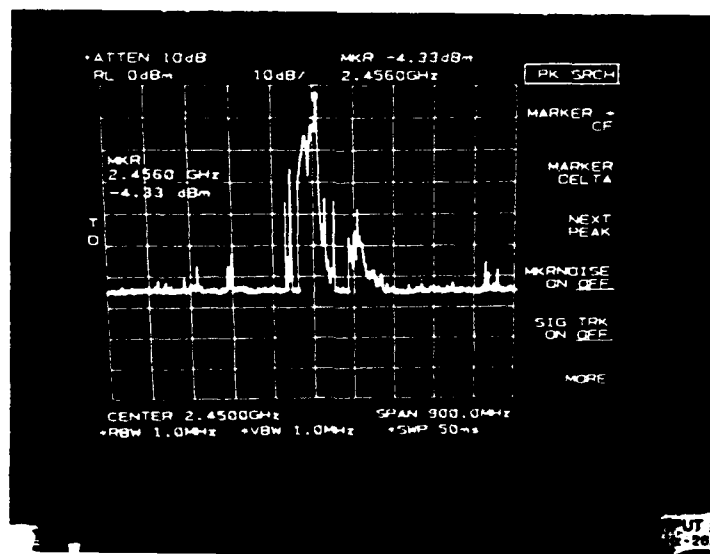
Figure 5-3 shows a graphical display of the $\pm \text{Avg. Terror}$ as a function of the ideal (desired) ΔT . In this figure, the x-axis is ideal temperature change desired, and on the y-axis the $\pm \text{Avg. Terror}$ corresponding to the actual output temperature change. The ΔT_{max} and ΔT_{min} values are plotted about the ideal ΔT in **Figure 5-5**.

MARKER @ 2.45 GHz



Cavity 5dB/div Sweep 2.0 - 3.0

Figure 5-1a. Return Loss Data of Heating Chamber showing 15 dB Bandwidth of 200 MHz (x-axis = 100 MHz/division ; y-axis = 5 dB/division) .



100% 20s

Figure 5-1b. Frequency Spectrum Data of Microwave Generator output showing power concentration bandwidth of 100 MHz (x-axis = 90 MHz/division; y-axis = 10 dB/division).

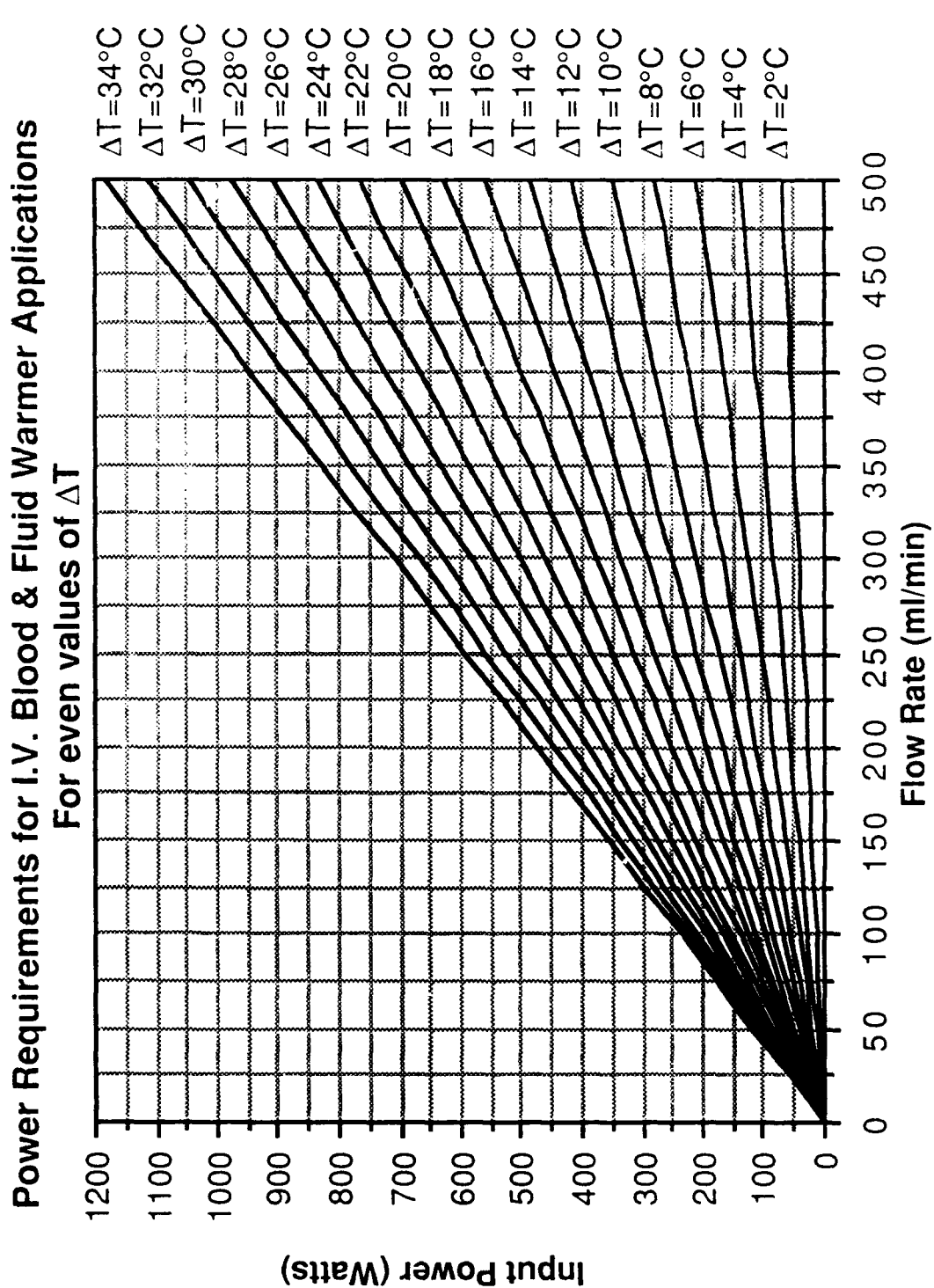


Figure 5-2. Graphical Representation of Ideal Power Values

Average Temperature Error as a Function of Temperature

Taken from Error Results in Table 1b.

Contract No. DAMD17-02-D-1011
Modification No. 000000
Annual Report No. 1

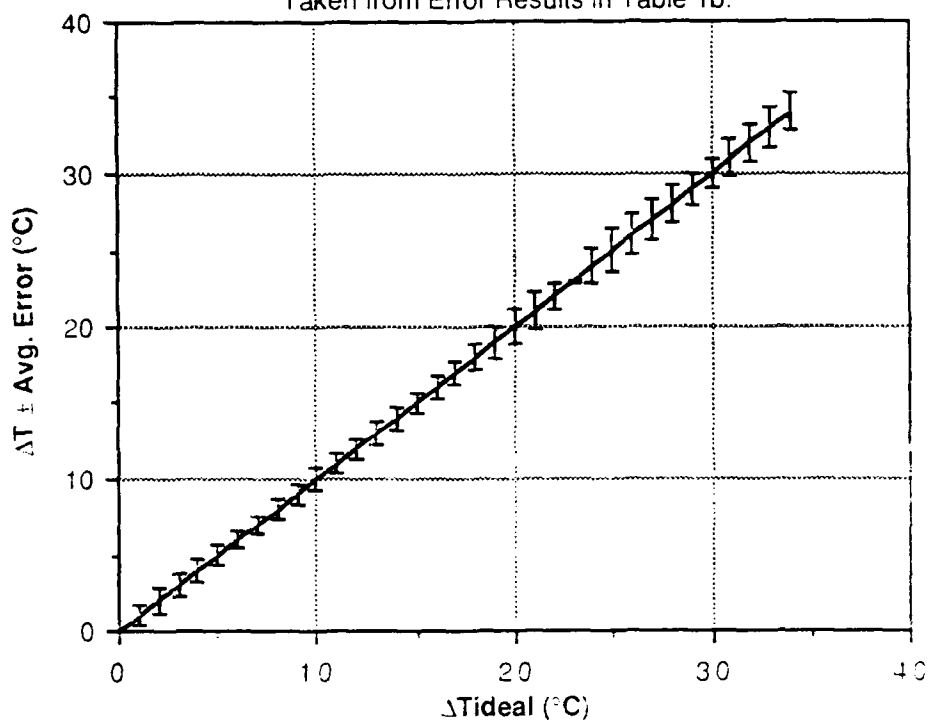


Figure 5-3. Graphical Average Error Results

Average Temperature Error as a function of Flow Rate

Taken from Avg. T error Results in Table 1b.

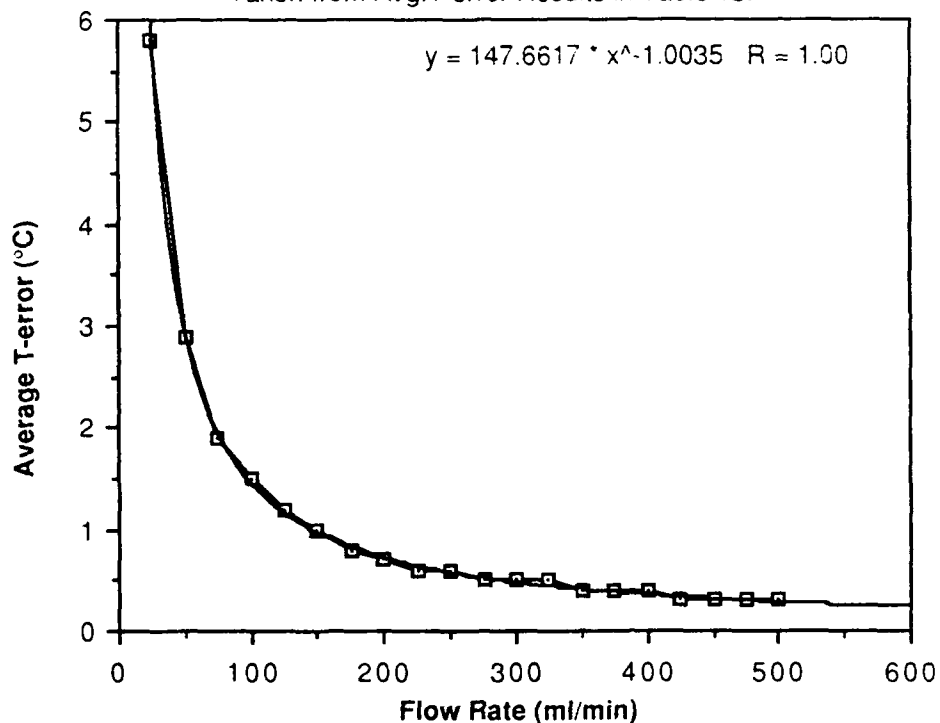


Figure 5-4. Graphical Average Error Results

ΔT_{\max} & ΔT_{\min} Calculated Error Data

Taken from Error Results in Table 1b.

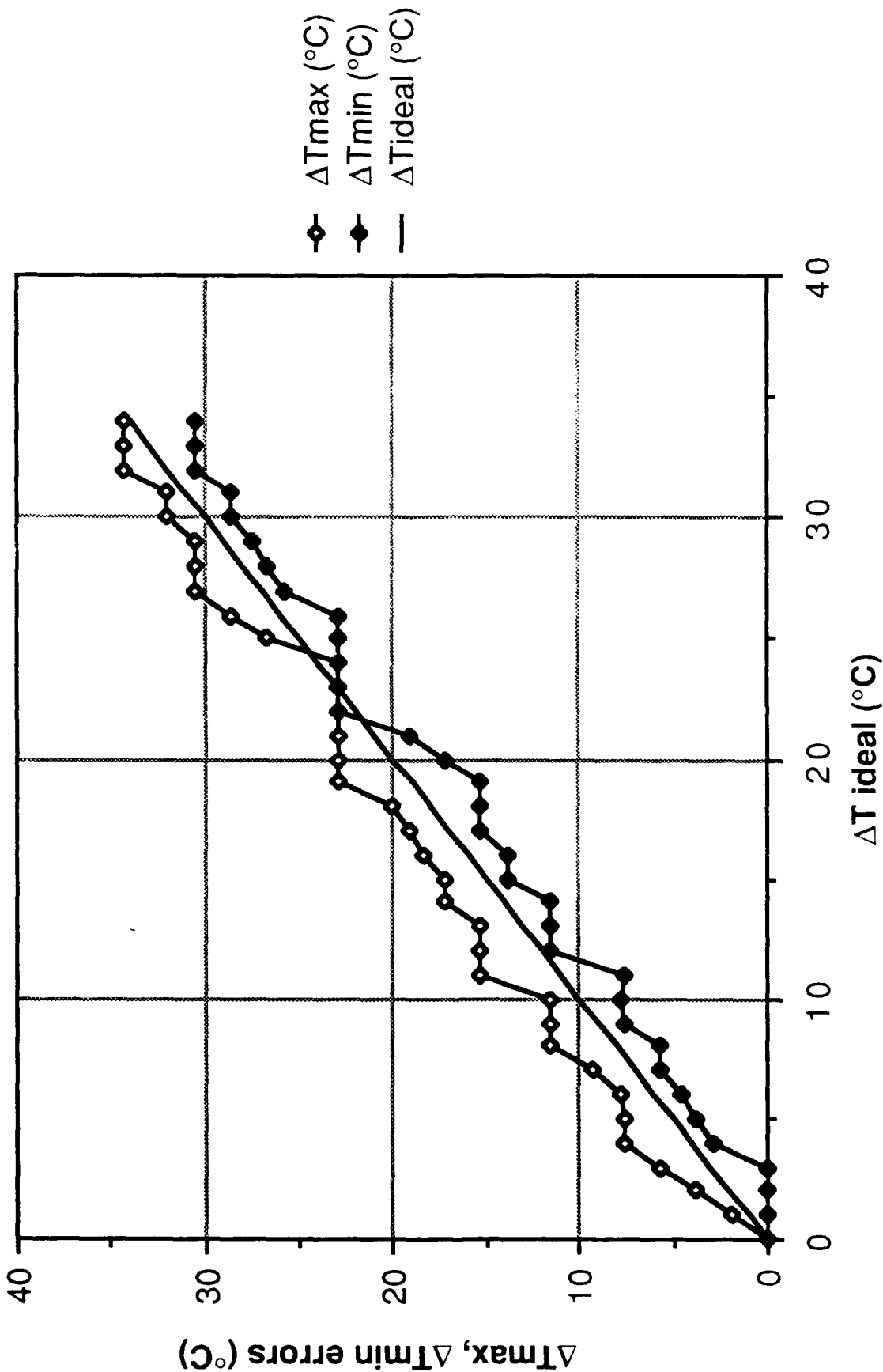


Figure 5-5. Graphical Max. & Min. Error Results

IDEAL POWER																			
Flow	$\Delta T=1^\circ$	$\Delta T=2^\circ$	$\Delta T=3^\circ$	$\Delta T=4^\circ$	$\Delta T=5^\circ$	$\Delta T=6^\circ$	$\Delta T=7^\circ$	$\Delta T=8^\circ$	$\Delta T=9^\circ$	$\Delta T=10^\circ$	$\Delta T=11^\circ$	$\Delta T=12^\circ$	$\Delta T=13^\circ$	$\Delta T=14^\circ$	$\Delta T=15^\circ$	$\Delta T=16^\circ$	$\Delta T=17^\circ$	$\Delta T=18^\circ$	$\Delta T=19^\circ$
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
25	1.8	3.5	5.2	7.0	8.7	10.5	12.2	14.0	15.7	17.4	19.2	20.9	22.7	24.4	26.2	27.9	29.6	31.4	33.2
50	3.5	7.0	10.5	14.0	17.5	20.9	24.4	27.9	31.4	34.9	38.4	41.9	45.3	48.8	52.3	55.8	59.3	62.8	66.3
75	5.3	10.4	15.7	20.9	26.2	31.4	36.6	41.9	47.1	52.3	57.5	62.8	68.0	73.2	78.5	83.7	88.9	94.1	99.4
100	7.0	13.9	20.9	27.9	34.9	41.8	48.8	55.8	62.8	69.7	76.7	83.7	90.6	97.6	104.6	111.6	118.5	125.5	132.5
125	8.8	17.4	26.1	34.9	43.6	52.3	61.0	69.8	78.5	87.1	95.9	104.6	113.3	122.0	130.8	139.5	148.1	156.9	165.6
150	10.5	20.9	31.4	41.9	52.4	62.7	73.2	83.7	94.2	104.6	115.1	125.6	135.9	146.4	156.9	167.4	177.8	188.3	198.8
175	12.3	24.3	36.6	48.8	61.1	73.2	85.4	97.7	109.9	122.0	134.2	146.5	158.6	170.8	183.1	195.3	207.4	219.6	231.8
200	14.0	27.8	41.8	55.8	69.8	83.6	97.6	111.6	125.6	139.4	153.4	167.4	181.2	195.2	209.2	223.2	237.0	251.0	265.0
225	15.8	31.3	47.0	62.8	78.5	94.1	109.8	125.6	141.3	156.8	172.6	188.3	203.9	219.6	235.4	251.1	266.6	282.4	298.2
250	17.5	34.8	52.3	69.8	87.3	104.5	122.0	139.5	157.0	174.3	191.8	209.3	226.5	244.0	261.5	279.0	296.3	313.8	331.3
275	19.3	38.2	57.5	76.7	96.0	115.0	134.2	153.5	172.7	191.7	210.9	230.2	249.2	268.4	287.7	306.9	325.9	345.1	364.3
300	21.0	41.7	62.7	83.7	104.7	125.4	146.4	167.4	188.4	209.1	230.1	251.1	271.8	292.8	313.8	334.8	355.5	376.5	397.5
325	22.8	45.2	67.9	90.7	113.4	135.9	158.6	181.4	204.1	226.5	249.3	272.0	294.5	317.2	340.0	362.7	385.1	407.9	430.7
350	24.5	48.7	73.2	97.7	122.2	146.3	170.8	195.3	219.8	244.0	268.5	293.0	317.1	341.6	366.1	390.6	414.8	439.3	463.8
375	26.3	52.1	78.4	104.6	130.9	156.8	183.0	209.3	235.5	261.4	287.6	313.9	339.8	366.0	392.3	418.5	444.4	470.6	496.8
400	28.0	55.6	83.6	111.6	139.6	167.2	195.2	223.2	251.2	278.8	306.8	334.8	362.4	390.4	418.4	446.4	474.0	502.0	530.0
425	29.8	59.1	88.8	118.6	148.3	177.7	207.4	237.2	266.9	296.2	326.0	355.7	385.1	414.8	444.6	474.3	503.6	533.4	563.2
450	31.5	62.6	94.1	125.6	157.1	188.1	219.6	251.1	282.6	313.7	345.2	376.7	407.7	439.2	470.7	502.2	533.3	564.8	596.3
475	33.3	66.0	99.3	132.5	165.8	198.6	231.8	265.1	298.3	331.1	364.3	397.6	430.4	463.6	496.9	530.1	562.9	596.1	629.3
500	35.0	69.5	104.5	139.5	174.5	209.0	244.0	279.0	314.0	348.5	383.5	418.5	453.0	488.0	523.0	558.0	592.5	627.5	662.5

AVAILABLE POWER (10 LEVELS, 400 W)																			
Flow	$\Delta T=1^\circ$	$\Delta T=2^\circ$	$\Delta T=3^\circ$	$\Delta T=4^\circ$	$\Delta T=5^\circ$	$\Delta T=6^\circ$	$\Delta T=7^\circ$	$\Delta T=8^\circ$	$\Delta T=9^\circ$	$\Delta T=10^\circ$	$\Delta T=11^\circ$	$\Delta T=12^\circ$	$\Delta T=13^\circ$	$\Delta T=14^\circ$	$\Delta T=15^\circ$	$\Delta T=16^\circ$	$\Delta T=17^\circ$	$\Delta T=18^\circ$	$\Delta T=19^\circ$
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40
75	0	0	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
100	0	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
125	0	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
150	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
175	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
200	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
225	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
250	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
275	0	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
300	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
325	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
350	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
375	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
400	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
425	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
450	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
475	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
500	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40

POWER ERROR = (IDEAL POWER - AVAILABLE)																			
Flow	$\Delta T=1^\circ$	$\Delta T=2^\circ$	$\Delta T=3^\circ$	$\Delta T=4^\circ$	$\Delta T=5^\circ$	$\Delta T=6^\circ$	$\Delta T=7^\circ$	$\Delta T=8^\circ$	$\Delta T=9^\circ$	$\Delta T=10^\circ$	$\Delta T=11^\circ$	$\Delta T=12^\circ$	$\Delta T=13^\circ$	$\Delta T=14^\circ$	$\Delta T=15^\circ$	$\Delta T=16^\circ$	$\Delta T=17^\circ$	$\Delta T=18^\circ$	$\Delta T=19^\circ$
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
25	1.8	3.5	5.2	7.0	8.7	10.5	12.2	14.0	15.7	17.4	19.2	-19.1	-17.4	-15.6	-13.9	-12.1	-10.4	-8.6	-6.8
50	3.5	7.0	10.5	14.0	17.5	-19.1	-15.6	-12.1	-8.6	-5.2	-1.7	1.9	5.3	8.8	12.3	15.8	19.3	-17.3	-13.8
75	5.3	10.4	15.7	-19.1	-13.8	-8.7	-3.4	1.9	7.1	12.3	17.5	-17.2	-12.1	-6.8	-1.6	3.7	8.9	14.1	19.3
100	7.0	13.9	-19.1	-12.1	-5.1	1.8	8.8	15.8	-17.2	-10.3	-3.3	3.7	10.6	17.6	-15.4	-8.4	-1.5	5.5	12.5
125	8.8	17.4	-13.9	-5.1	3.6	12.3	-19.0	-10.3	-1.5	7.1	15.9	-15.4	-6.8	2.0	10.8	19.5	-11.9	-3.1	5.5
150	10.5	-19.2	-8.7	1.9	12.4	-17.3	-6.8	3.7	14.2	-15.5	-5.0	5.6	15.9	-13.6	-3.1	7.4	17.8	-11.8	-1.1
175	12.3	-15.7	-3.4	8.8	-18.9	-6.9	5.4	17.7	-10.1	2.0	14.2	-13.5	-1.5	10.8	-17.0	-4.7	7.4	19.6	-8.8
200	14.0	-12.2	1.8	15.8	-10.2	3.6	17.6	-8.4	5.6	19.4	-6.6	7.4	-18.8	-4.8	9.2	-16.8	-3.0	11.0	-1.5
225	15.8	-8.7	7.0	-17.2	-1.5	14.1	-10.2	5.6	-18.7	-3.2	12.6	-11.7	3.9	19.6	-4.7	11.1	-13.4	2.4	18.8
250	17.5	-5.3	12.3	-10.3	7.3	-15.5	2.0	19.5	-3.0	14.3	-8.3	9.3	-13.5	4.0	-18.5	-1.0	16.3	-6.3	11.1
275	19.3	-1.8	17.5	-3.3	16.0	-5.1	14.2	-6.6	12.7	-8.3	10.9	-9.8	9.2	-11.6	7.7	-13.1	5.9	-14.9	4.4
300	-19.0	1.7	-17.3	3.7	-15.3	5.4	-13.6	7.4	-11.6	9.1	-9.9	11.1	-8.2	12.8	-6.2	14.8	-4.5	16.5	-2.2
325	-17.3	5.2	-12.1	10.7	-6.6	15.9	-1.4	-18.7	4.1	-13.5	9.3	-8.0	14.5	-2.8	20.0	2.7	-14.9	7.9	18.8
350	-15.5	8.7	-6.9	17.7	2.2	-13.7	10.8	-4.7	19.8	4.0	-11.6	13.0	-2.9	-18.4	6.1	-9.4			
375	-13.8	12.1	-1.6	-15.4	10.9	-3.3	-17.0	9.3	-4.5	-18.6	7.6	-6.1	19.8	6.0	-7.8				
400	-12.0	15.6	3.6	-8.4	19.6	7.2	-4.8	-16.8	11.2	-1.2	-13.2	14.8	2.4	-9.6					
425	-10.3	19.1	8.8	-1.4	-11.7	17.7	7.4	-2.9	-13.1	16.2	6.0	-4.3	-15.0						
450	-8.5	-17.5	14.1	5.6	-3.0	-11.9	19.6	11.1	2.6	-6.4	-14.9	16.7	7.7						
475	-6.8	-14.0	19.3	12.5	5.8	-1.5	-8.2	-15.0	18.3	11.1	4.3	-2.4							
500	-5.0	-10.5	-15.5	19.5	14.5	9.0	4.0	-1.0	-6.0	-11.5	-16.5								

Table 1a. Calculated Power Data for Engineering Model A. 10-L

POWER																																	
AT=18°		AT=19°		AT=20°		AT=21°		AT=22°		AT=23°		AT=24°		AT=25°		AT=26°		AT=27°		AT=28°		AT=29°		AT=30°		AT=31°		AT=32°		AT=33°		AT=34°	
0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
9.6	31.4	33.1	34.9	36.6	38.4	40.1	41.9	43.6	45.3	47.1	48.8	50.6	52.3	54.1	55.8	57.5	59.3																
9.3	62.8	66.3	69.8	73.2	76.7	80.2	83.7	87.2	90.7	94.2	97.6	101.1	104.6	108.1	111.6	115.1	118.6																
6.9	94.1	99.4	104.6	109.8	115.1	120.3	125.6	130.7	136.0	141.2	146.4	151.7	156.9	162.2	167.3	172.6	177.8																
18.5	125.5	132.5	139.5	146.4	153.4	160.4	167.4	174.3	181.3	188.3	195.2	202.2	209.2	216.2	223.1	230.1	237.1																
18.1	156.9	165.6	174.4	183.0	191.8	200.5	209.3	217.9	226.6	235.4	244.0	252.8	261.5	270.3	279.1	287.6	296.4																
7.8	188.3	198.8	209.3	219.6	230.1	240.6	251.1	261.5	272.0	282.5	292.8	303.3	313.8	324.3	334.7	345.2	355.7																
67.4	219.6	231.9	244.1	256.2	268.5	280.7	293.0	305.0	317.3	329.5	341.6	353.9	366.1	378.4	390.4	402.7	414.9																
7.0	251.0	265.0	279.0	292.8	306.8	320.8	334.8	348.6	362.6	376.6	390.4	404.4	418.4	432.4	446.2	460.2	474.2																
66.6	282.4	298.1	313.9	329.4	345.2	360.9	376.7	392.2	407.9	423.7	439.2	455.0	470.7	486.5	502.0	517.7	533.5																
6.3	313.8	331.3	348.8	366.0	383.5	401.0	418.5	435.8	453.3	470.8	488.0	505.5	523.0	540.5	557.8	575.3	592.8																
5.9	345.1	364.4	383.6	402.6	421.9	441.1	460.4	479.3	498.6	517.8	536.8	556.1	575.3	594.6	613.5	632.8	652.0																
55.5	376.5	397.5	418.5	439.2	460.2	481.2	502.2	522.9	543.9	564.9	585.6	606.6	627.6	648.6	669.3	690.3	711.3																
5.1	407.9	430.6	453.4	475.8	498.6	521.3	544.1	566.5	589.2	612.0	634.4	657.2	679.9	702.7	725.1	747.8	770.6																
4.8	439.3	463.8	488.3	512.4	536.9	561.4	585.9	610.1	634.6	659.1	683.2	707.7	732.2	756.7	780.9	805.4	829.9																
4.4	470.6	496.9	523.1	549.0	575.3	601.5	627.8	653.6	679.9	706.1	732.0	758.3	784.5	810.8	836.6	862.9	889.9																

[illegible][illegible]

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TEMPERATURE ERROR = (POWER ERROR X 60) - (4.184 X FLOW)																				
Flow	$\Delta T=1^\circ$	$\Delta T=2^\circ$	$\Delta T=3^\circ$	$\Delta T=4^\circ$	$\Delta T=5^\circ$	$\Delta T=6^\circ$	$\Delta T=7^\circ$	$\Delta T=8^\circ$	$\Delta T=9^\circ$	$\Delta T=10^\circ$	$\Delta T=11^\circ$	$\Delta T=12^\circ$	$\Delta T=13^\circ$	$\Delta T=14^\circ$	$\Delta T=15^\circ$	$\Delta T=16^\circ$	$\Delta T=17^\circ$	$\Delta T=18^\circ$	$\Delta T=19^\circ$	$\Delta T=20^\circ$
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
25	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
50	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
75	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
100	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
125	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
150	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
175	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
200	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
225	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
250	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
275	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
300	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
325	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
350	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
375	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
400	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
425	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
450	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
475	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9
500	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	-10.9	-10.0	-8.9	-7.9	-6.9	-6.0	-4.9	-3.9	-2.9

ACTUAL TEMPERATURE CHANGE = (IDEAL TEMPERATURE - TEMPERATURE																				
Flow	$\Delta T=1^\circ$	$\Delta T=2^\circ$	$\Delta T=3^\circ$	$\Delta T=4^\circ$	$\Delta T=5^\circ$	$\Delta T=6^\circ$	$\Delta T=7^\circ$	$\Delta T=8^\circ$	$\Delta T=9^\circ$	$\Delta T=10^\circ$	$\Delta T=11^\circ$	$\Delta T=12^\circ$	$\Delta T=13^\circ$	$\Delta T=14^\circ$	$\Delta T=15^\circ$	$\Delta T=16^\circ$	$\Delta T=17^\circ$	$\Delta T=18^\circ$	$\Delta T=19^\circ$	$\Delta T=20^\circ$
25	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	22.9	23.0	22.9	22.9	22.9	23.0	22.9	22.9	22.9
50	0.0	0.0	0.0	0.0	0.0	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5	22.9	22.9
75	0.0	0.0	0.0	0.0	0.0	7.7	7.7	7.7	7.7	7.7	7.7	15.3	15.3	15.3	15.3	15.3	15.3	15.3	15.3	22.9
100	0.0	0.0	0.0	0.0	0.0	5.7	5.7	5.7	5.7	5.7	5.7	11.5	11.5	11.5	11.5	11.5	11.5	11.5	11.5	22.9
125	0.0	0.0	0.0	0.0	0.0	4.6	4.6	4.6	4.6	4.6	4.6	9.2	9.2	9.2	9.2	9.2	9.2	9.2	9.2	22.9
150	0.0	0.0	0.0	0.0	0.0	3.8	3.8	3.8	3.8	3.8	3.8	7.7	7.7	7.7	7.7	7.7	7.7	7.7	7.7	22.9
175	0.0	0.0	0.0	0.0	0.0	3.3	3.3	3.3	3.3	3.3	3.3	6.6	6.6	6.6	6.6	6.6	6.6	6.6	6.6	22.9
200	0.0	0.0	0.0	0.0	0.0	2.9	2.9	2.9	2.9	2.9	2.9	5.7	5.7	5.7	5.7	5.7	5.7	5.7	5.7	22.9
225	0.0	0.0	0.0	0.0	0.0	2.6	2.6	2.6	2.6	2.6	2.6	5.1	5.1	5.1	5.1	5.1	5.1	5.1	5.1	22.9
250	0.0	0.0	0.0	0.0	0.0	2.3	2.3	2.3	2.3	2.3	2.3	4.6	4.6	4.6	4.6	4.6	4.6	4.6	4.6	22.9
275	0.0	0.0	0.0	0.0	0.0	2.1	2.1	2.1	2.1	2.1	2.1	4.2	4.2	4.2	4.2	4.2	4.2	4.2	4.2	22.9
300	0.0	0.0	0.0	0.0	0.0	1.9	1.9	1.9	1.9	1.9	1.9	3.8	3.8	3.8	3.8	3.8	3.8	3.8	3.8	22.9
325	0.0	0.0	0.0	0.0	0.0	1.8	1.8	1.8	1.8	1.8	1.8	3.5	3.5	3.5	3.5	3.5	3.5	3.5	3.5	22.9
350	0.0	0.0	0.0	0.0	0.0	1.6	1.6	1.6	1.6	1.6	1.6	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3	22.9
375	0.0	0.0	0.0	0.0	0.0	1.5	1.5	1.5	1.5	1.5	1.5	3.1	3.1	3.1	3.1	3.1	3.1	3.1	3.1	22.9
400	0.0	0.0	0.0	0.0	0.0	1.4	1.4	1.4	1.4	1.4	1.4	2.9	2.9	2.9	2.9	2.9	2.9	2.9	2.9	22.9
425	0.0	0.0	0.0	0.0	0.0	1.3	1.3	1.3	1.3	1.3	1.3	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	22.9
450	0.0	0.0	0.0	0.0	0.0	1.3	1.3	1.3	1.3	1.3	1.3	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6	22.9
475	0.0	0.0	0.0	0.0	0.0	1.2	1.2	1.2	1.2	1.2	1.2	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	22.9
500	0.0	0.0	0.0	0.0	0.0	1.1	1.1	1.1	1.1	1.1	1.1	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3	22.9
$\Delta T=$	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0	16.0	17.0	18.0	19.0	20.0

Error Results																				
ΔT_{max}	1.9	3.8	5.7	7.6	9.5	11.4	13.3	15.2	17.1	19.0	20.9	22.8	24.7	26.6	28.5	30.4	32.3	34.2	36.1	38.0
ΔT_{min}	0.0	0.0	0.0	2.9	4.8	6.7	8.6	10.5	12.4	14.3	16.2	18.1	20.0	21.9	23.8	25.7	27.6	29.5	31.4	33.3
\pm Avg. T error °C	0.7	0.8	0.8	0.7	0.7	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.8	0.7	0.8	0.8	0.9	1.0	1.2

*Row rates of 25 & 50 ml/min were omitted

Table 1b. Calculated Temperature Errors of Engineering Model A. with 10-Level Feed

[illegible][illegible]

19.1	20.1	22.9	23.0	22.9	22.9	22.9	26.8	28.7	30.6	30.6	30.6	32.1	32.1	34.4	34.4	34.4
15.3	15.1	17.2	19.1	22.9	22.9	22.9	22.9	22.9	25.8	26.8	27.5	28.7	28.7	30.6	30.6	30.6
0.9	1.0	1.2	1.2	0.9	0.1	1.1	1.5	1.3	1.3	1.2	1.0	1.0	1.2	1.2	1.3	1.2

Model A, with 10-Level Feedback Power Control.

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Modification No P9003
Annual Report No 1

5.3 Temperature Monitoring and Response Time

Table 2 shows a summary of data taken with different integration time constants on the Radiometer output. The experimental setup consisted of two I.V. fluid bags hung from the I.V. Stand of Engineering Model A, one bag was at room temperature of 23.0°C while the other bag was warmed in a temperature controlled oven to 28.0°C. The two bags were connected with I.V. tubing to the two inlets of a 3-way stopcock, while the output of the stopcock was fed through the temperature monitoring transducer with Silicone tubing (0.12" I.D. x 0.19" O.D.) which was connected to the Radiometer. The fluid from the room temperature bag was allowed to flow with gravity (280 ml/min), and the radiometric output record was initiated. After approximately 3 seconds, the stopcock was turned to allow the flow of the warm fluid, 30.0°C, through the transducer and the radiometric output response was recorded on a HP7046B X-Y Recorder.

The response time of the Radiometer for each time constant setting is the duration of time to reach 90% of the final steady-state output value, in this case corresponding to 30 °C. The resolution of the Radiometer is then established as follows:

- Calculated from output data: $\Delta \text{Voltage}/1^\circ\text{C} = 92 \text{ millivolts}/1^\circ\text{C}$
- Measured from output data: Peak to peak noise voltage for each integration time constant setting as shown in **Table 2**.
- **Resolution = (Signal Noise) \div (92mV/1°C).**
For example an integration time constant set to 0.5 seconds (as for Engineering Model A), yields an output signal noise of 30 mV, therefore Resolution can be calculated: $(30 \text{ mV}) \div (92\text{mV}/1^\circ\text{C}) = 0.3^\circ\text{C}$.

Thus, the criteria for resolution is that the minimum discernible signal is equal to that signal which is just above the signal noise such that, the highest peaks of the noise are at the same level as the lowest peaks of the signal. With the data of **Table 2**, the maximum amount of fluid (I.V. or blood) that could pass through the outlet temperature transducer in the event of misuse, before system shut-down occurs, can be calculated as follows for any given flow rate:

Example: **Flow** = 250 ml/min = 4.2 ml/second
Time Constant internally set to 0.1 seconds
Response Time = 0.4 seconds (see **Table 2**.)
Resolution = 0.9 seconds (see **Table 2**.)

$$(4.2 \text{ milliliters/s}) \times (0.4 \text{ seconds}) = 1.7 \text{ milliliters}$$

NOTE: A Volume of 1.7 ml which occupies approximately ten inches of I.V. tubing

The data in **Table 2**, shows that the non-invasive radiometric technique can track changes in temperature very rapidly. A resolution approaching 0.2 °C can be achieved with a response time of 2.3 seconds. This is suitable for fine measurement of temperature. For coarse, extremely rapid measurement of temperature, a response time of 0.4 seconds can be achieved with a resolution of 0.9°C. These fast response rates are essential to provide an effective feedback mechanism for controlling energy supplied to the heating chamber, while the finer resolution is needed to maintain constant outlet temperatures. The Radiometer is equipped to handle both these requirements with two separate outputs which may be individually selected to provide quick response times coupled with fine resolution of outlet temperature. Optimization of response time and resolution with the operation of the digital feedback control system will be performed in year #2 of this Phase 2 Program.

TIME CONSTANT integration time seconds	SIGNAL NOISE peak-to-peak voltage millivolts	TEMPERATURE RESOLUTION °C	RESONSE TIME time to 90% of peak seconds
0.1	8.0	0.90	0.4
0.5	3.0	0.30	1.3
1.0	2.0	0.20	2.3
1.5	1.5	0.15	3.2
2.0	1.0	0.10	4.2

Table 2. Resolution and Response time of Inlet/Outlet Transducer for a Flow Rate = 280 ml/min

5.4 In-Vivo Testing Protocol

In-Vivo animal experiments were conducted by the Surgical Research Laboratories, Department of Surgery at New England Medical Center in Boston, Massachusetts.

The aim of these experiments was to determine whether microwave heating of blood using a prototype blood warming device results in an abnormal decrease in survival of the cellular elements of fresh blood in a primate model (baboon) when compared to blood warmed in a water bath.

Experimental Protocol:

Three adult male baboons were used for these studies. Each baboon underwent an experiment in which a sample of fresh blood containing radiolabeled cells was subjected to microwave heating from approximately 4-6°C to 37°C during injection through the prototype device at a flow rate of 250ml/minute. A similar control experiment in which warming in a water bath replaced microwave heating followed for each baboon at a time when all cell-associated radioactivity had returned to baseline levels.

Under general anesthesia (pentobarbital IV), fresh blood was drawn from the baboon and anticoagulated with ACD. The white blood cells (WBC), platelets and red blood cells (RBC) were separated according to established procedures. Technetium-99m, Iodine-125, and Chromium-51 were used to label the separated WBCs, platelets and RBCs respectively. Iodine-125 labeled fibrinogen was also prepared and following the radiolabeling procedure, the separated cells were pooled together. The blood sample containing the labeled cells was cooled to 4°C and then warmed to 37°C using either microwave heating or a water bath for "uWave Heated" and "Control" experiments respectively.

Estimation of Cell Survival:

1ml blood samples were drawn at intervals for 28 days following re-injection of the radiolabeled blood. Gamma activity associated with each separate radioisotope circulating was quantified by altering the window on the gamma counter. This enabled simultaneous measurement of the different cell-associated radioisotopes present in each 1ml blood sample. Gamma counts were corrected mathematically for natural decay. Cell survivals were expressed as a percentage of the total gamma counts injected. Summarized results are presented in tabular and graphic form.

5.5 In-Vivo Testing Results

The results of this study are based on the premise that grossly damaged cells would be removed from the circulating blood volume by the reticuloendothelial system. Previous *in-vitro* studies performed in Phase I revealed that no gross biochemical evidence of red cell destruction occurs when microwave heating is performed. The theory that more subtle forms of red cell damage might be present, yet not manifested biochemically, is thus considered. Removal of the cells by the reticuloendothelial system might therefore represent evidence of more subtle injury. **Figures 5-6 and 5-7** compare the half like decay curves for red blood cells labelled with Chromium-51.

Bearing in mind that this blood has been separated, radiolabeled, and reconstituted, there is no difference in the half time survival of cell associated counts in the blood stream when comparing microwave blood with controlled blood. **Figures 5-8, 5-9 and 5-10** demonstrate the half time survival curves for Indium labelled platelets in the three baboons studied. Again, there is no difference in the disappearance of platelet associated counts. As expected, the decay of platelet activity occurs much more rapidly than that observed in the red cell population. **Figures 5-11, 5-12 and 5-13**, demonstrate the decay pattern of the Technetium-99m labelled white blood cells. There appears to be greater variability in this data, however, these differences represent very small changes in actual cell survival, with, in one case the microwave cells surviving longer, and in two cases the controlled cells, demonstrating more hardy survival. These results need to be interpreted in the light that in transfusions with packed red cells, no white cell activity is expected on a practical basis from these transfusions. Finally, **Figures 5-14 and 5-15** demonstrate the half time decay of ¹²⁵I labelled fibrinogen. The microwave preparation had a slight increase in sustained counts, however, these difference are not significant.

The tabular data for all these studies are presented in the Appendix.

Conclusions to Date:

- 1) No significant difference in survival of white cells and platelets in blood subjected to microwave heating to 37°C was observed compared to blood heated in a water bath for all three baboons.
- 2) No significant differences in survival of red cells or fibrinogen in blood subjected to microwave heating to 37°C was observed compared to blood heated in a water bath for two baboons. Completed results for the third animal will be available in the near future.
- 3) *In-vitro* and *in-vivo* studies to date, demonstrate no significant hemolysis of blood preparations passed through the microwave prototype device.

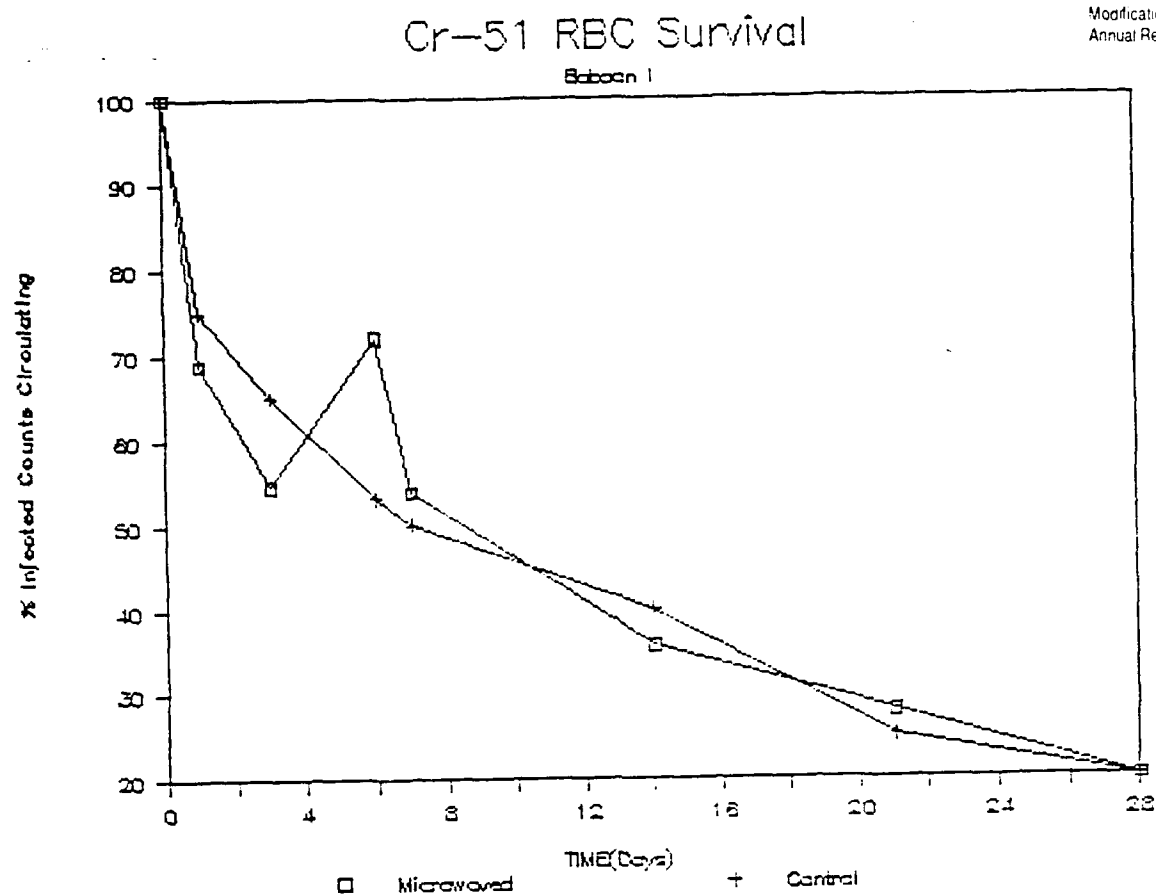


FIGURE 5-6: RBC Survival - Baboon I

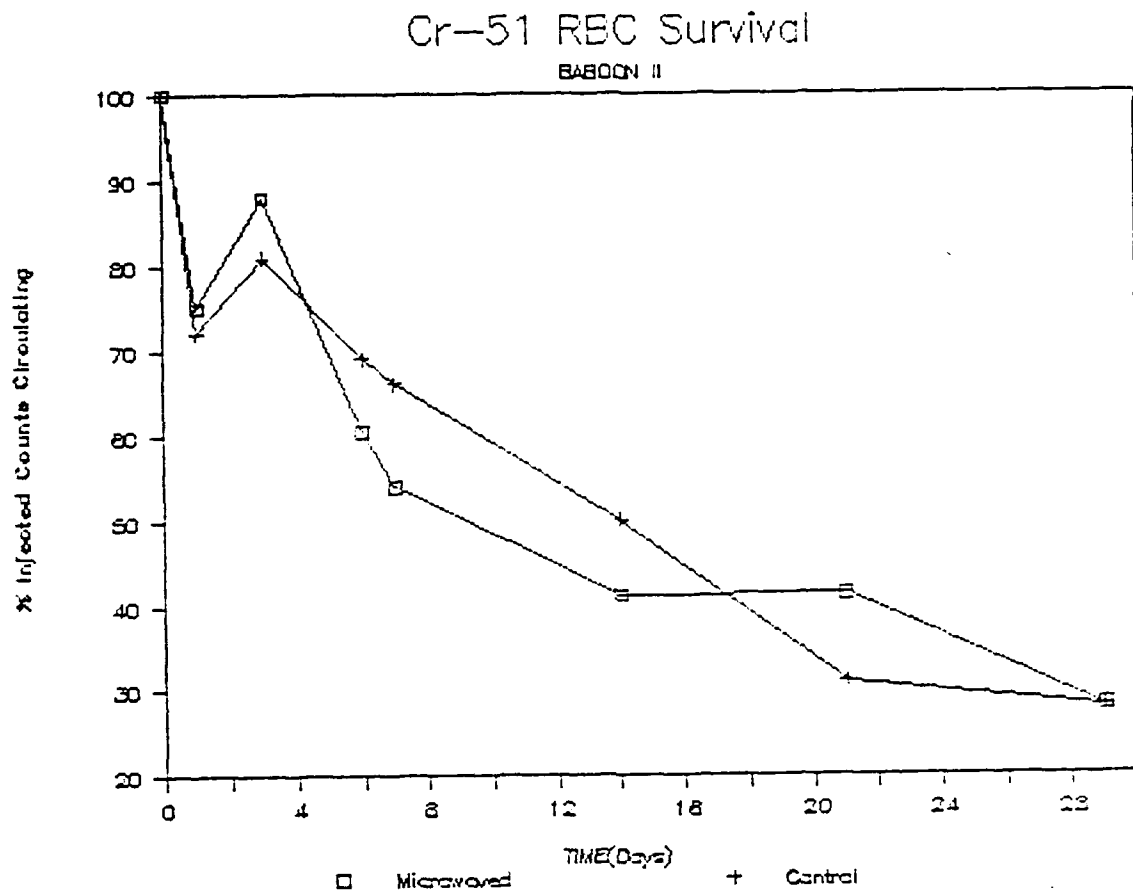


FIGURE 5-7: RBC Survival - Baboon II

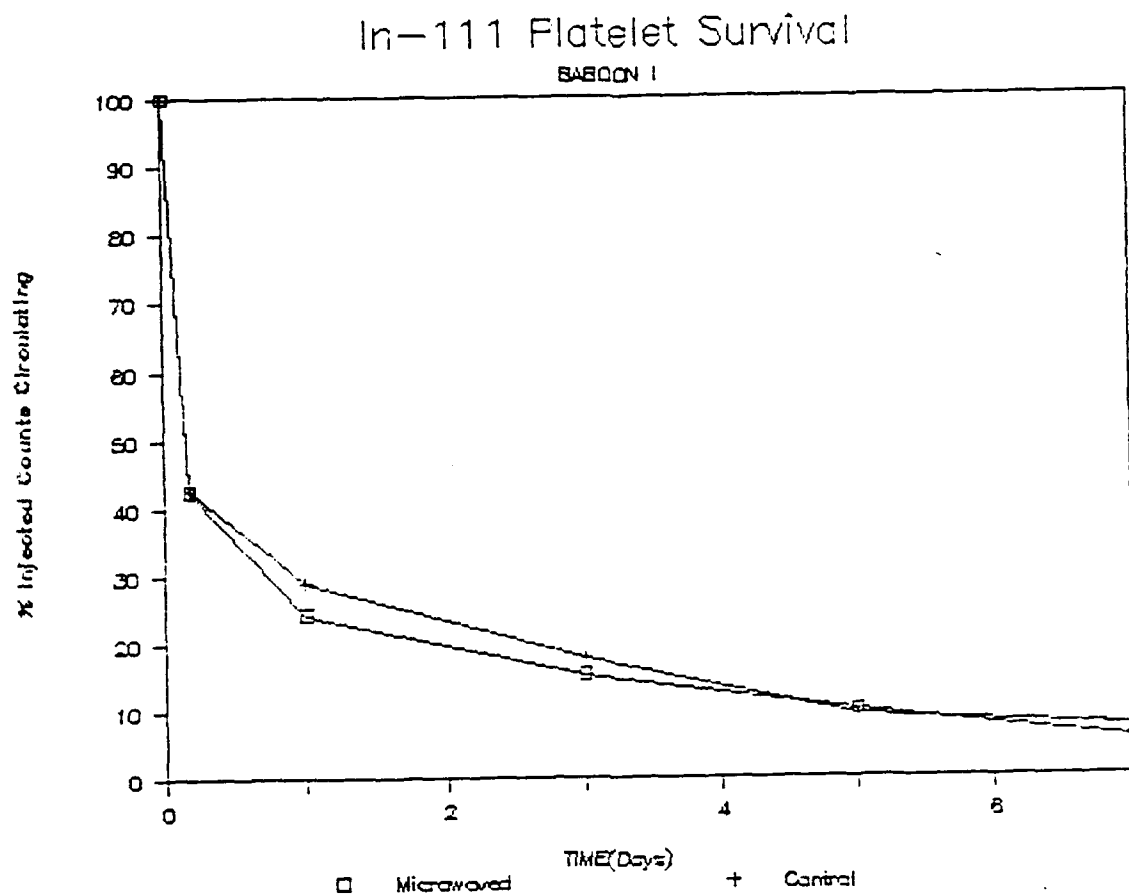


FIGURE 5-8: Platelet Survival - Baboon I

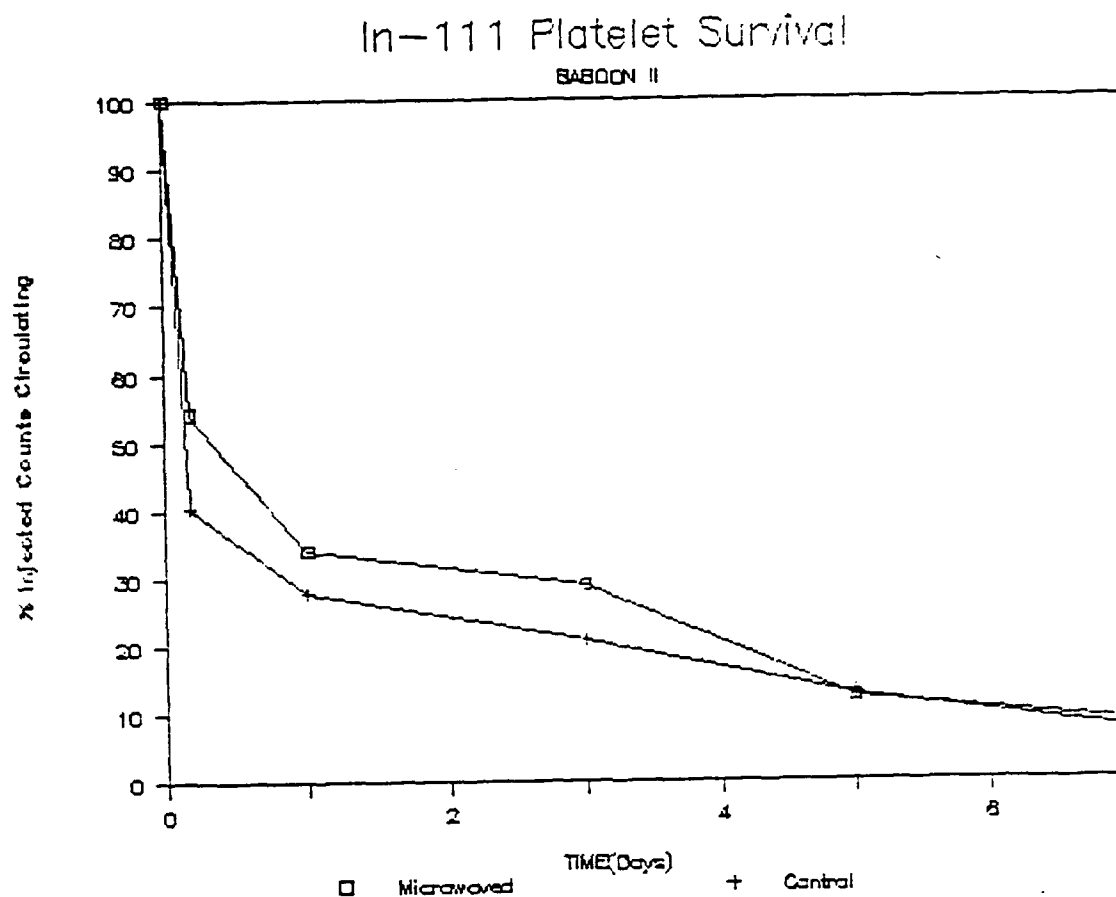


FIGURE 5-9: Platelet Survival - Baboon II

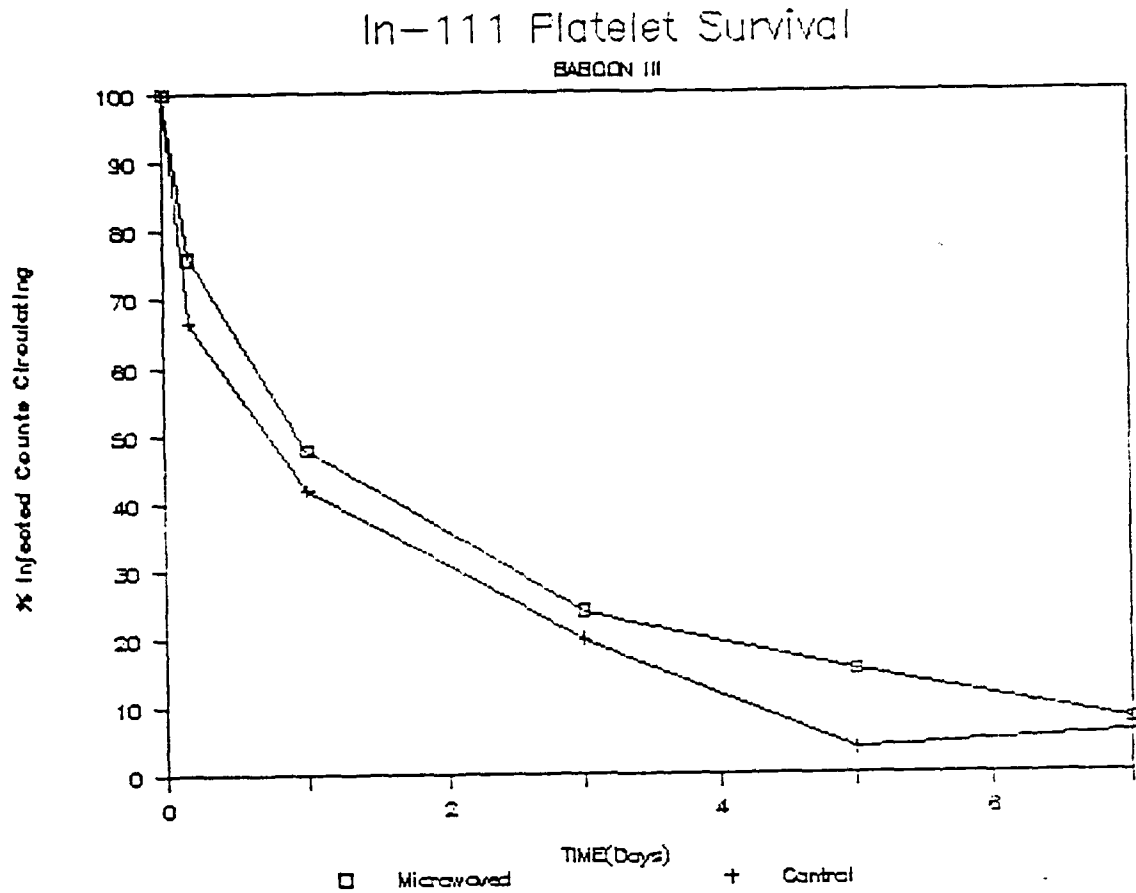


FIGURE 5-10: Platelet Survival - Baboon III

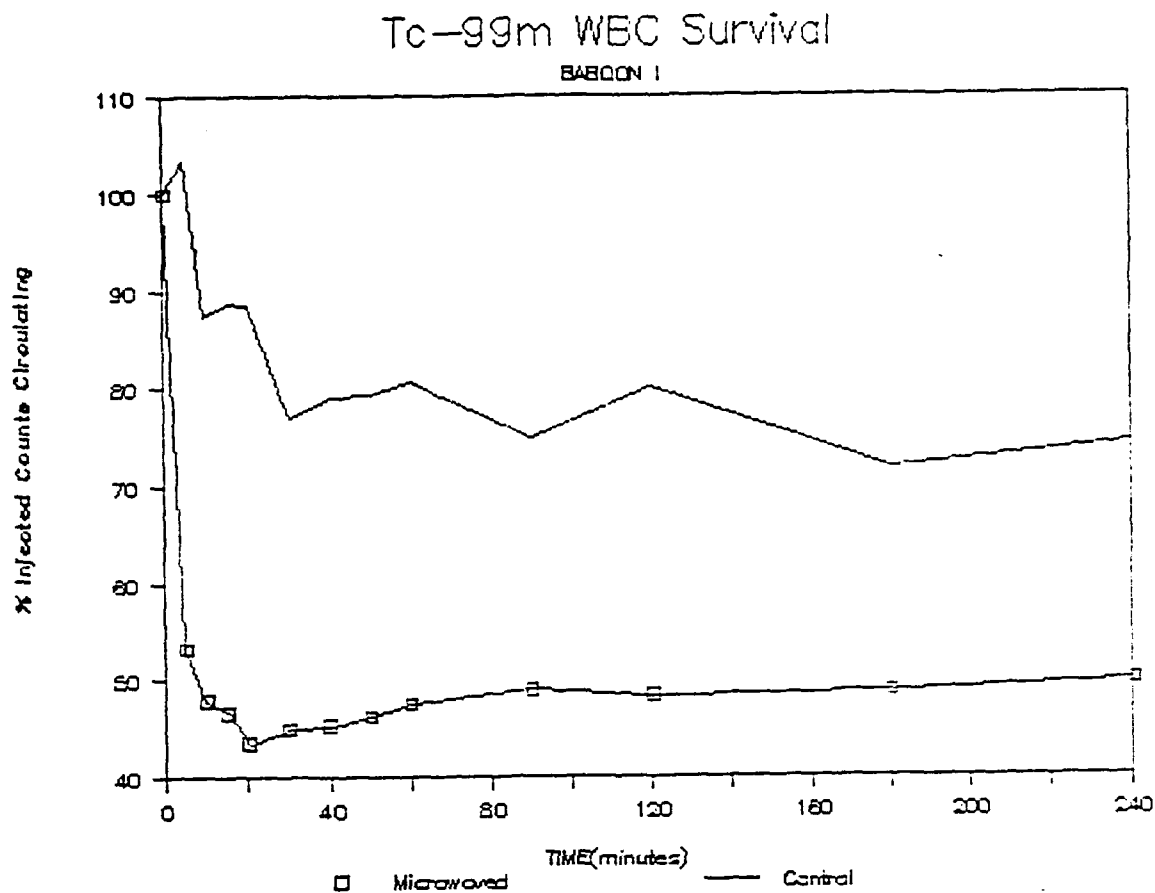


FIGURE 5-11: WBC Survival - Baboon I

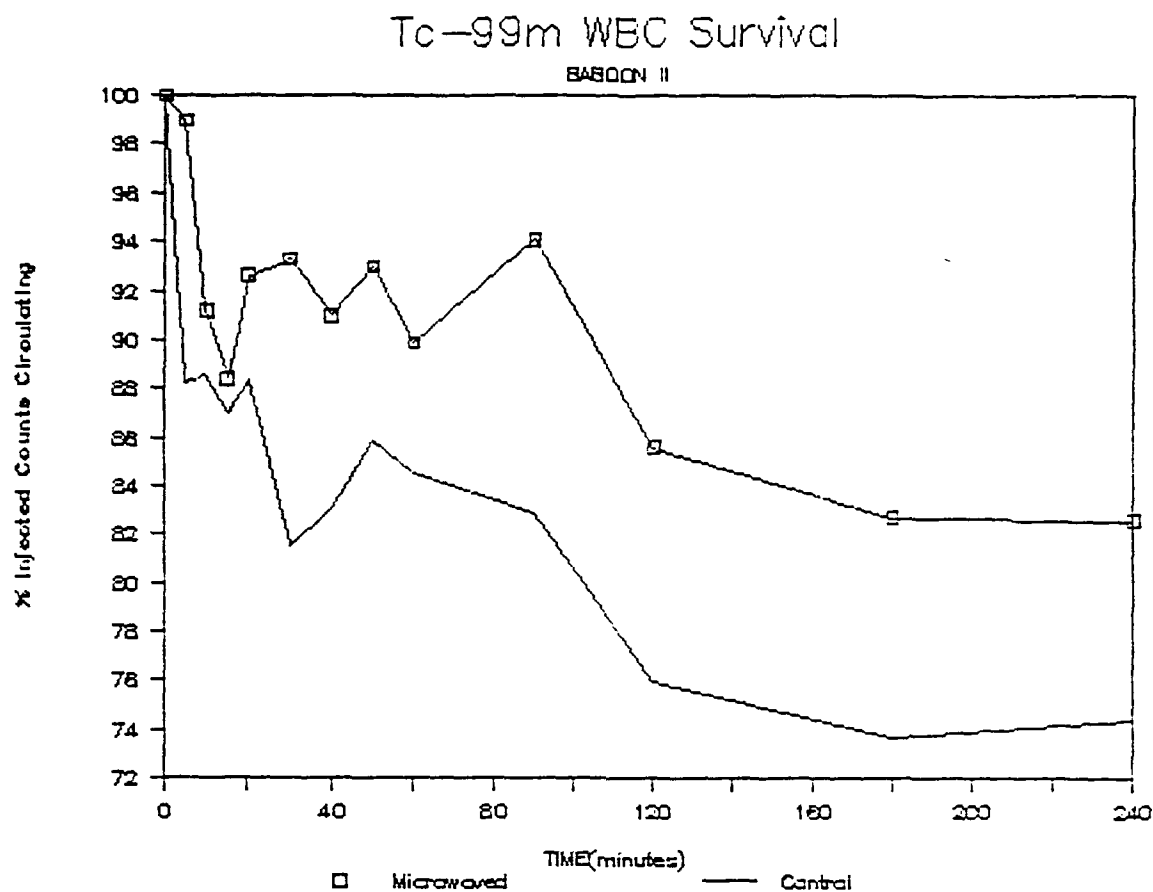


FIGURE 5-12: WBC Survival - Baboon II

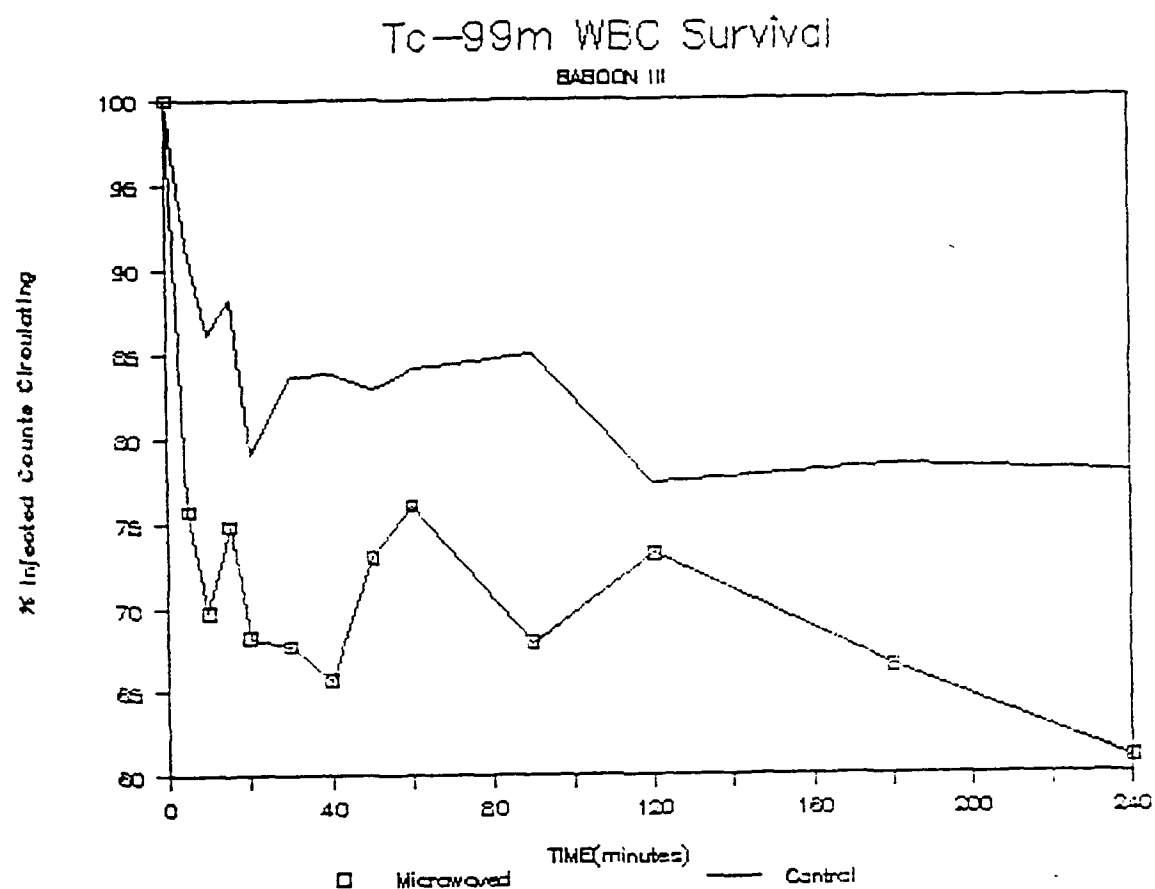


FIGURE 5-13: WBC Survival - Baboon III

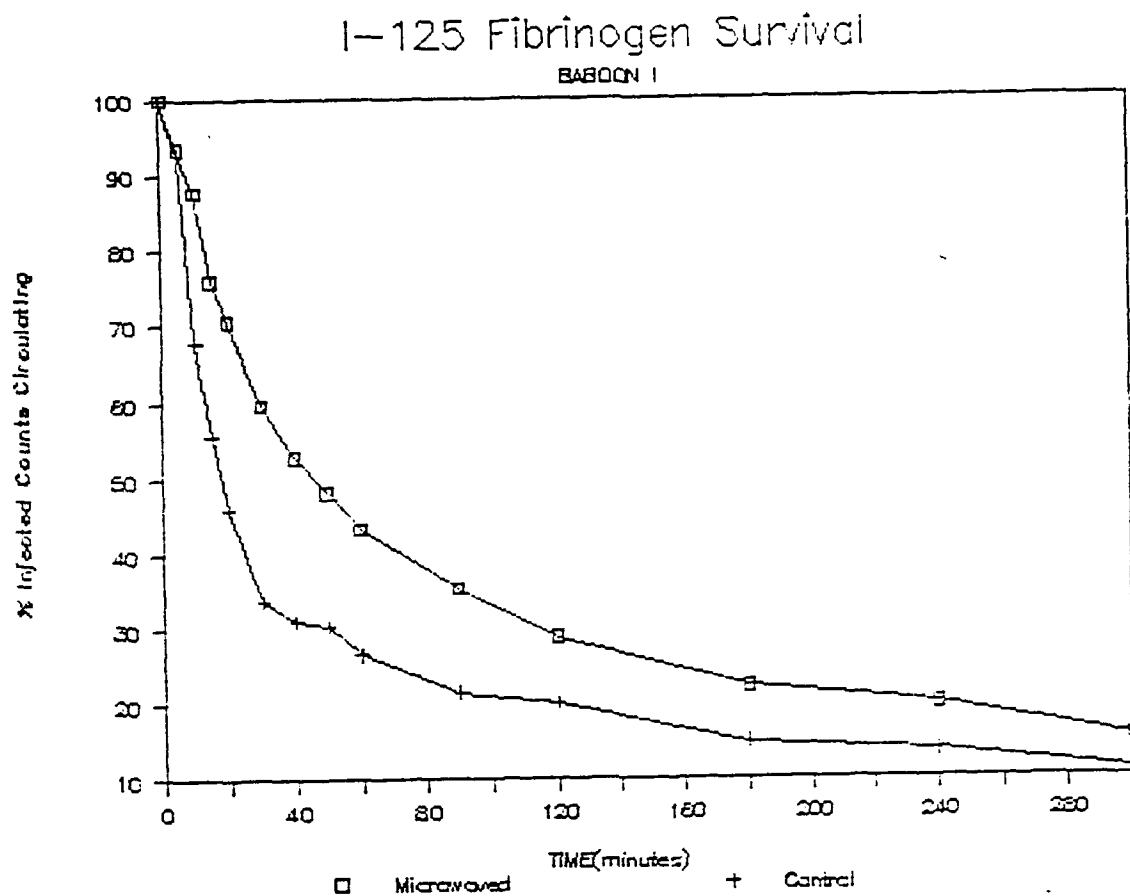


FIGURE 5-14: Fibrinogen Survival - Baboon I

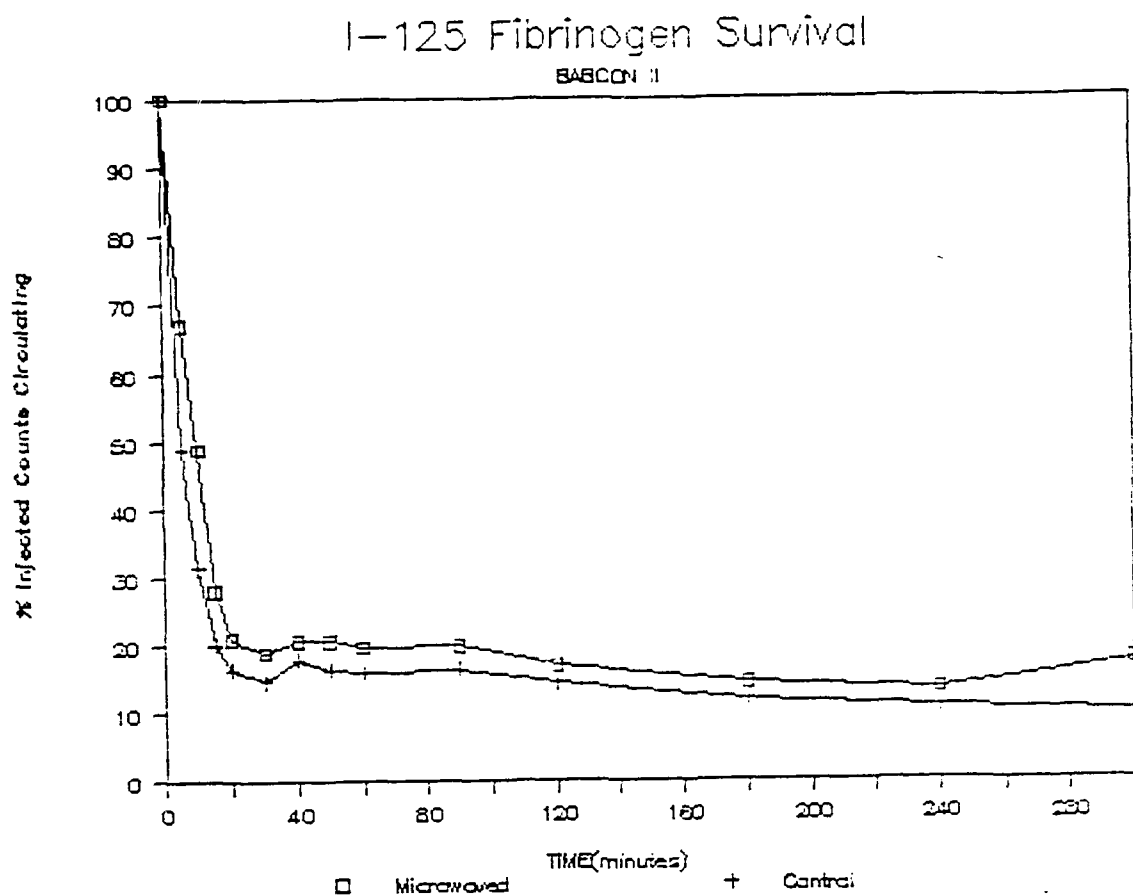


FIGURE 5-15: Fibrinogen Survival - Baboon II

6.0 SUMMARY OF SALIENT RESULTS

Engineering Model A, successfully completed in year#1, is a functional system that demonstrates that the microwave heating and temperature monitoring technique developed by Microwave Medical Systems, Inc. can be integrated into a feedback controlled closed-loop system for rapid, uniform and controlled fluid warming. Secondly, it has been shown through *in-vivo* animal experiments that the microwave warming technique is efficacious and efficient for in-line warming of blood during the infusion process.

6.1 Design, Development and Fabrication of the Feedback Controlled System

Engineering Model A, shown in the Photograph of **Figure 6-1**, has been successfully completed to meet the objectives of the first year of the Phase 2 program. This unit consists of a feedback control mechanism implemented using an IBM PC computer that links together the microwave energy source with the microwave radiometric temperature measurement system. The support hardware and software that has been designed, developed and implemented to achieve the closing of the feedback loop includes:

- (1) Microwave Energy Source Module to Supply 400 watts of Microwave Energy at 2.45 GHz
- (2) Heating Chamber that directs microwave warming energy to the fluid-filled IV tubing Cartridge
- (3) Cartridge of IV Tubing that can be inserted into the Heating Chamber
- (4) Microwave Interface Module that connects the Microwave Energy Source to the Heating Chamber
- (5) Power Control Module to vary power levels of the Microwave Energy Source
- (6) Computer Output Interface Module to link the IBM PC to the Power Control Module
- (7) Computer Input Interface Module to link the IBM PC to the Radiometer Temperature Monitor
- (8) Temperature Monitoring Transducers to link the Radiometer to inlet and outlet fluid ports
- (9) Feedback Control Algorithm Software to implement ALGORITHM#1 on the IBM PC
- (10) Display Software to graphically display system input and output values in real-time

The Power Control Module has been designed to vary the power output of the microwave energy source with 10 levels of control: from a minimum of 0 watts to a maximum of 400 watts in increments of 40 watts. Using a feedback control algorithm implemented in software on the IBM PC computer, a control voltage is supplied to the power control module from the IBM PC as a function of the fluid temperature as measured by the radiometric temperature monitoring module. Using this method of control the output temperature of the fluid flowing through the system at a rate of approximately 200 ml/min can be maintained at a given target temperature (e.g., 37°C) with a tolerance of $\pm 1.5^\circ\text{C}$ when fluid temperature is elevated by an increment of 1°C to 33°C (i.e. from a starting temperature range of 4°C to 36°C to a target temperature of 37°C). This tolerance will be improved to $\pm 1^\circ\text{C}$ in year#2 of the Phase 2 program by providing a finer level of control, i.e., 20 levels of control versus the existing 10 control levels.

A typical sample of the output displayed in real-time on the graphics screen of the IBM PC computer when **Engineering Model A** is in operation is shown in **Figure 6-2**.

6.2 Efficacy of Heating Blood with the Microwave Warming Device

• Restatement of Results from the Phase I Program

Blood samples were run through the system at various flow-rates. Samples were run through the system under four conditions:

- 1) Control (Unheated): Run through the system once with power off
- 2) One-Pass Heating: Run through the system once with power on
- 3) Two-Pass Heating: Run through the system twice with power on
- 4) Three-Pass Heating: Run through the system thrice with power on

For one-pass heating, examination of the results of blood samples showed no significant differences in hematologic data were produced from that of the control(unheated) samples. The biochemical aspects also showed the absence of any statistically significant differences between the control and the one-pass samples.

The only statistically significant difference found for two-pass and three-pass heating was in Lactic acid dehydrogenase(LDH), the absolute levels of which were clinically normal. Changes recorded here maybe attributable to increased handling of the samples or to heating effects alone, and not necessarily to any effects caused by microwave heating.

• Results from *In-vivo* Animal(baboon) Study Performed during Year#1 of Phase 2

The first *in-vivo* tests using the microwave warming technique have been performed during in year#1 of Phase 2 by collaborators in the Department of Surgery at New England Medical Center using baboons as the test subjects.

The tests involved withdrawing a sample of whole fresh blood from a baboon with a syringe. This syringe of blood was anticoagulated, centrifuged and prepared for radiolabeling of red blood cells, white blood cells, platelets and fibrinogen. The labeled blood components were then recombined and then passed thru the microwave heating device, as depicted in **Figure 2.**, to achieve a temperature rise of at least 20°C, to a maximum of 37°C. [NOTE: Before being heated by the microwave device, the blood sample was first cooled in an ice bath to guarantee that the starting temperature would be less than 15°C].

The total volume of labeled blood components used for the tests was approximately 35 ml. This labeled blood was mixed with unlabeled whole blood from the baboon to yield a grand total volume of approximately 100 ml. This total volume was divided into two 50 ml syringes to be used for microwave warming. Two syringes were made available, to provide for a spare sample in case of a mishap in the experimental procedure.

The blood components are labeled as follows:

COMPONENT	ISOTOPE	DOSE
RBC	Chrom-51	30 µCi
WBC	Tc-99	3.1 µCi
Fibrinogen	Iodine-125	140 µCi
Platelets	Indium-111	136.7 µCi

The blood sample, thus, is subjected to a single-pass thru the test fixture and then returned, intravenously, to the donor. A control preparation is produced in identical fashion except that heating will occur in a water bath to raise the temperature to 37°C. The viability of this most fragile component of the blood is assessed by following the half life of these cells in the blood stream using gamma camera imaging and the ability of these level components to participate in plug formation during standard bleeding time test.

The experiments performed included three microwave warming tests of blood withdrawn from baboons and three control tests using a heated water bath to warm the blood. The data suggest that cellular elements of the blood warmed by the microwave process have an appropriate persistence in the blood stream that is no different from that found with the control samples.

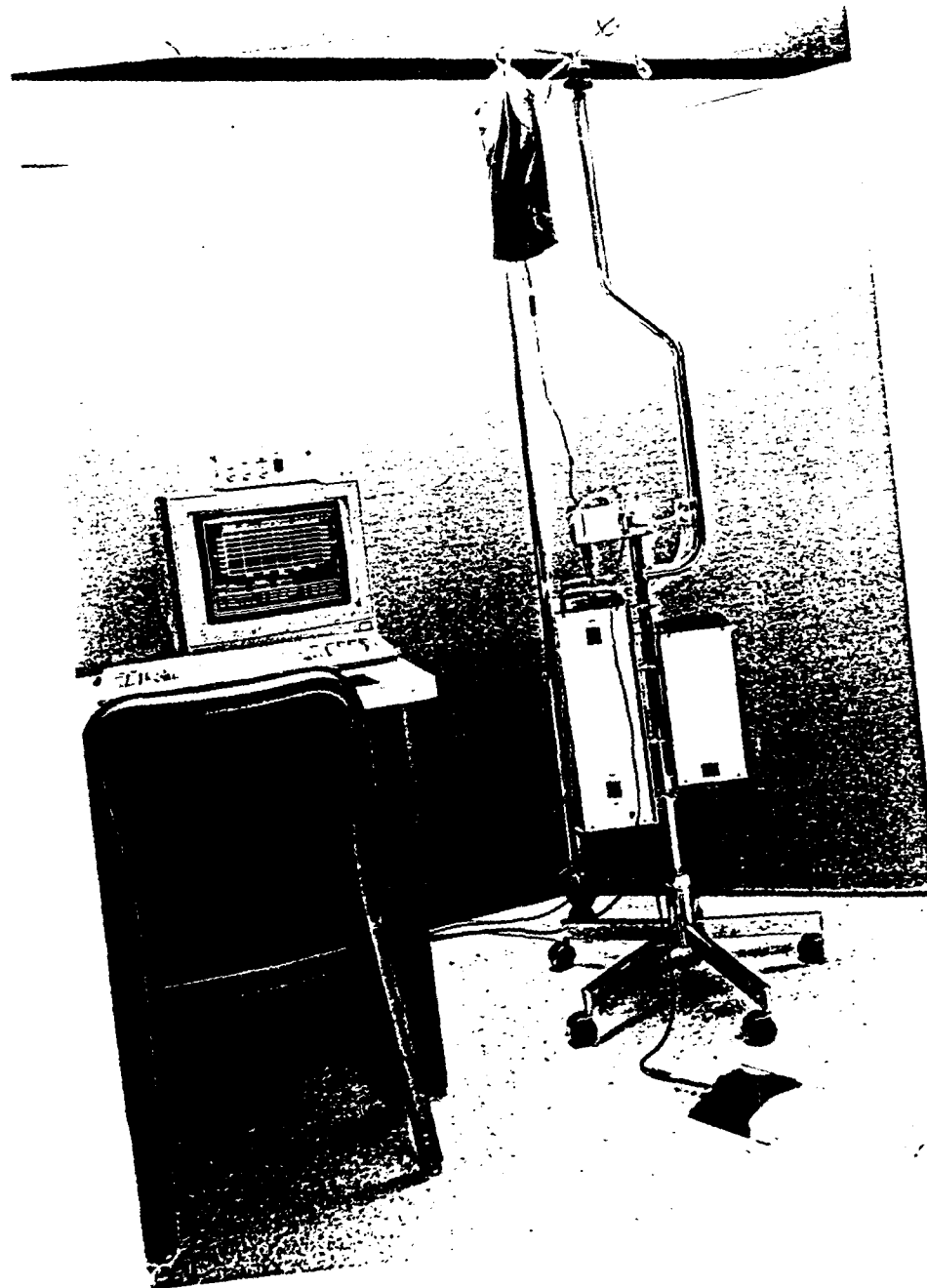
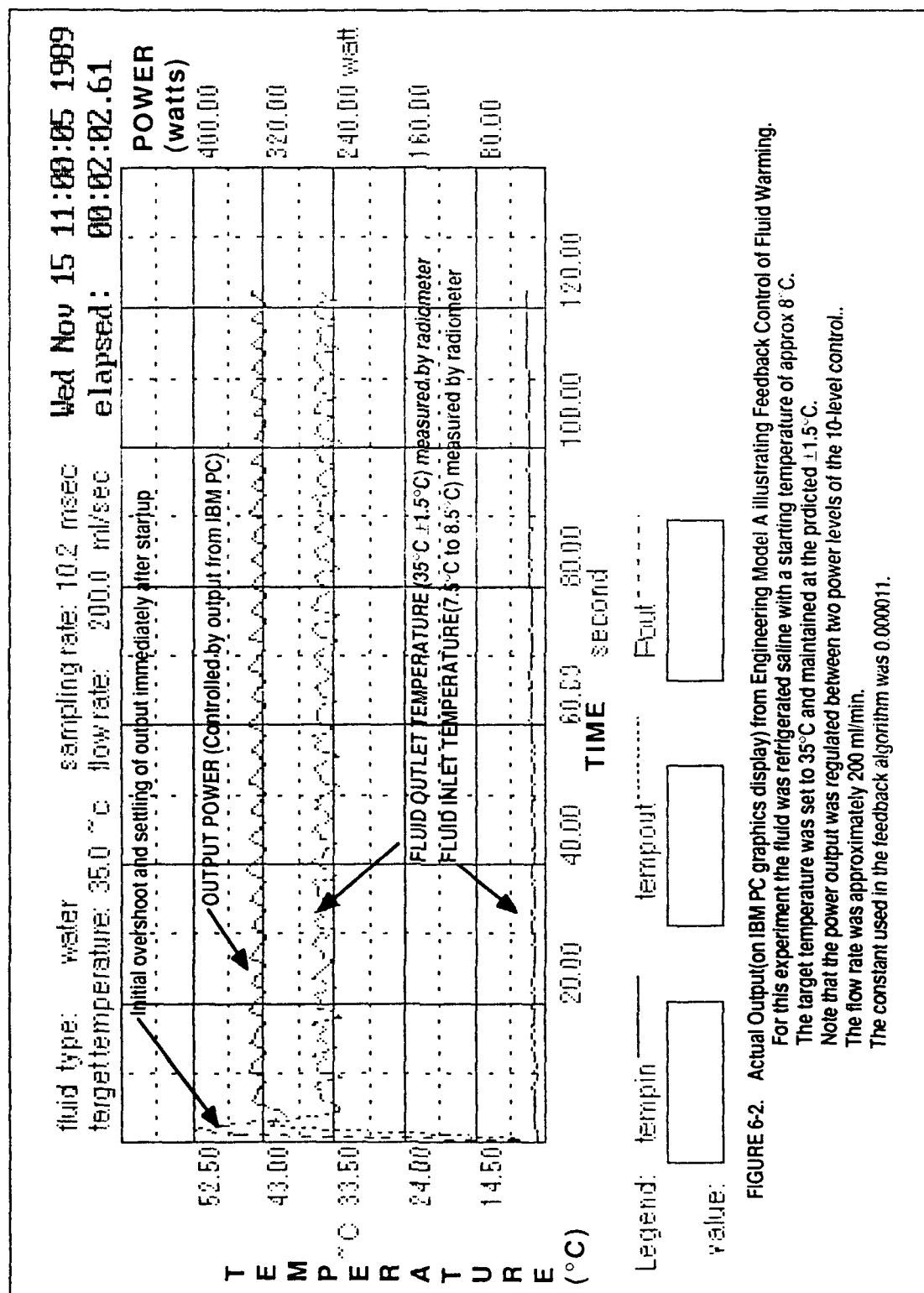


FIGURE 6-1. Photograph of Engineering Model A (fully functional)



7.0 CONCLUSIONS

The *in-vivo* animal test results have confirmed previously conducted (in Phase 1 of this program) *in-vitro* test results that our technique of single-pass in-line microwave heating of blood does not affect the constituency of blood components differently than samples heated with conventional water bath techniques.

Several technical issues were resolved during this first year of the Phase 2 program:

- The variable power control technique developed here is sufficient to hold outlet temperatures to a target temperature within $\pm 1.5^{\circ}\text{C}$ at a typical flow rate of 200 ml/min. Further development in year#2 will achieve finer control, in the order of $\pm 1^{\circ}\text{C}$.
- The microwave power module of 400 watts used in Engineering Model A is sufficient to elevate the temperature of flowing fluids by a $\Delta T = 33^{\circ}\text{C}$ (e.g. from 4°C to 37°C) at flow rates of upto 150 ml/min. Increase in power output will allow equivalent elevations ($\Delta T = 33^{\circ}\text{C}$) in fluid temperature at correspondingly higher flow rates.
- Radiometric temperature monitoring at the inlet and outlet ports of the heating chamber is possible without interference from the microwave energy source.
- Radiometric temperature monitoring has a response time that is sufficient to respond to the rapid change of temperature provided by the microwave power source.

All but one of the major technical issues addressed in the first year of this Phase 2 program were successfully. The one remaining technical issue from year#1 to be carried over to year#2 is: Measurement of fluid temperature internal to the Heating Chamber. This issue will be addressed in the second year of the Phase 2 program as discussed in **Section 4.1** of this report.

8.0 RECOMMENDATIONS

Based on the performance of Engineering Model A developed during year#1 of this program the following recommendations are being made for work to continue in year#2:

- The variable power control technique developed in year#1 will be refined to provide a finer control of the fluid outlet temperature. In Engineering Model A the goal will be to hold the fluid outlet temperature at a given target temperature within a range of $\pm 1.0^{\circ}\text{C}$.
- Engineering Model B is targeted to provide the following minimal fluid warming capabilities:
The elevation of refrigerated fluid at 4°C or higher to a target temperature of 37°C or lower at flow rates of 250 ml/min or less.

In order to accomplish this capability, the microwave power module of 400 watts used in Engineering Model A will be replaced with a 700 watt power module in Engineering Model B.

- A technique using the monitoring of reflected power from the heating chamber will be investigated as an alternative method of determining the fluid temperature internal to the Heating Chamber.
- The insertable cartridge is being developed so that it can be packaged in the future as a sterile disposable.
- The packaging of Engineering Model B will be oriented toward attaching the system components to an IV stand similar to that shown in **Figure 6-1**.
- Additional meetings between MMS and US Army personnel during the second year of development would be helpful in establishing further guidelines for system development to address the needs of the US Army.

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APPENDIX

Tabulation of *In-Vivo* Test Results for Survival Study of Microwave Heated Blood

Microwave Blood Warming Experiments.

June-December 1989

Cr-51 RBC Survival Studies.

TIME (min)	Baboon I		Baboon II		Baboon III	
	uW-Heat	Control	uW-Heat	Control	uW-Heat	Control
	(% Injected Counts Circulating)				(Due to finish 12-13-89)	
0	100	100	100	100	100	
5	88.3	95	90.3	106	92.7	
10	86	93	112.3	94	81.7	
15	86	88	36.5	100	100.6	
20	86.3	90	101.5	100	91.2	
30	81.5	88	94.5	100	74.4	
40	86.8	83	98.7	109	86.7	
50	82.3	90	104.3	103	85.2	
60	91.2	85	104.1	91	82.6	
90	86	83	109.1	91	83.3	
120	89.4	95	111.9	91	90.5	
180	85.5	85	97.6	88	92.1	
240	90.1	90	108.3	91	90.2	
300	87.6	90	110.2	106		
1440	68.7	75	75	72	73.8	
4320	54.5	65	87.9	81	66.7	
7200	71.8	53	60.3	69	68.6	
10080	53.7	50	53.9	66	64.1	
20160	35.6	40	41	50	38.4	
30240	27.9	25	41.2	31	28.3	
40320	20.1	20	28.2	28	31.1	

Days	Baboon I		Baboon II		Baboon III	
	uW-Heat	Control	uW-Heat	Control	uW-Heat	Control
0	100	100	100	100	100	
1	68.7	75	75	72	73.8	
3	54.5	65	87.9	81	66.7	
5	71.8	53	60.3	69	68.6	
7	53.7	50	53.9	66	64.1	
14	35.6	40	41	50	38.4	
21	27.9	25	41.2	31	28.3	
28	20.1	20	28.2	28	31.1	

Microwave Blood Warming Experiments.

June-December 1989

In-111 Platelet Survival Studies.

TIME (min)	Baboon I		Baboon II		Baboon III	
	uW-Heat	Control	uW-Heat	Control	uW-Heat	Control
	(% Injected Counts Circulating)					
0	100	100	100	100	100	100
5	81.7	82.7	69.7	57	86.5	75.3
10	75.5	66.3	55.3	49.1	84.1	71.8
15	68.9	60.1	48	43.5	87.4	68.4
20	76.4	55.3	46.6	42.1	87.9	71.7
30	59.8	45.9	50.8	37.3	80.3	62
40	57.7	45.4	52.9	43.5	77.6	70.5
50	53.9	44.9	52.6	42.6	84.6	69.6
60	51.4	44.9	52.2	40.6	86.3	66.1
90	49.1	46.9	58.8	44.5	80.1	71.5
120	46.1	44	54.8	41.8	86.4	71.7
180	44.4	40.6	54.2	39.9	80	66.6
240	42.3	42.4	54.1	40.4	75.9	66.5
300	37.6		53.6	40.6		69.2
1440	24.2	28.8	34.1	27.8	47.7	41.8
4320	15.4	17.7	28.9	20.8	23.8	19.8
7200	10.1	9.3	12.3	12.8	15.3	3.7
10080	5.8	7.4	7.3	8.5	7.8	6.2

Days	Baboon I		Baboon II		Baboon III	
	uW-Heat	Control	uW-Heat	Control	uW-Heat	Control
0	100	100	100	100	100	100
0.17	42.3	42.4	54.1	40.4	75.9	66.5
1	24.2	28.8	34.1	27.8	47.7	41.8
3	15.4	17.7	28.9	20.8	23.8	19.8
5	10.1	9.3	12.3	12.8	15.3	3.7
7	5.8	7.4	8.5	7.3	7.8	6.2

Microwave Blood Warming Experiments.

June-December 1989

Tc-99m Labeled WBC Survival Results.

TIME (min)	Boon I		Boon II		Boon III	
	uW-Heat	Control	uW-Heat	Control	uW-Heat	Control
	(% Injected CTS Circulating)					
0	100	100	100	100	100	100
5	53.3	103.3	99	88.2	75.7	91.5
10	47.9	87.3	91.2	88.6	69.7	86.1
15	46.7	88.5	88.4	87	74.8	83.2
20	43.5	88.3	92.6	88.3	68.2	79.1
30	45	76.9	93.3	81.5	67.7	83.7
40	45.3	79.1	91	83.1	65.7	83.8
50	46.3	79.4	93	85.9	73	82.9
60	47.5	80.5	89.9	84.5	76	84.1
90	49	75	94.1	82.9	67.9	84.9
120	48.4	80.1	85.6	76	72.1	77.3
180	48.9	71.8	82.7	73.7	66.5	78.4
240	49.9	74.3	82.6	74.4	61	77.9
300	47.6		76.8	73.8		40.9
1440	27.3	41.6	42	44.4	36.9	40.5

Microwave Blood Warming Experiments.

June-December 1989

I-125 Fibrinogen Survival Studies.

TIME (min)	Baboon I		Baboon II		Baboon III	
	uW-Heat	Control	uW-Heat	Control	uW-Heat	Control
	(% Injected Counts Circulating)					(Due to finish 12-13-89)
0	100	100	100	100	100	
5	93.5	92.7	67.1	48.9	97.3	
10	87.8	67.7	48.8	31.3	95.2	
15	76	55.4	27.9	20.1	99.8	
20	70.6	45.9	20.9	16.5	94.3	
30	59.6	33.7	18.9	14.8	83.5	
40	52.8	31	20.6	17.9	86.8	
50	48.1	30.4	20.6	16.5	91.6	
60	43.3	26.6	19.6	15.9	91.6	
90	35.3	21.5	19.9	16.5	83.9	
120	28.8	20.1	16.9	14.3	86.8	
180	22.3	14.9	14.3	12.1	83.5	
240	19.9	13.6	13.3	10.7	76.6	
300	15.4	11.1	17.6	9.9	42.5	